

Exhibit 31

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: ACETAMINOPHEN –) MDL No. 3043
ASD-ADHD PRODUCTS)
LIABILITY LITIGATION) Case No.
) 1:22-md-03043-DLC

THIS DOCUMENT RELATES TO:)

) JUDGE DENISE
All Cases, 1:22-md-03043) COTE

THURSDAY, SEPTEMBER 7, 2023

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Videotaped deposition of Stephen V. Faraone, Ph.D., held at the offices of Skadden Arps, One Manhattan West, 395 9th Avenue, New York, New York, commencing at 8:35 a.m., on the above date, before Carrie A. Campbell, Registered Diplomat Reporter, Certified Realtime Reporter, Illinois, California & Texas Certified Shorthand Reporter, Missouri, Kansas, Louisiana & New Jersey Certified Court Reporter.

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| <p>1 785 "Oxidative Stress and ADHD: A 159 Meta-Analysis," Joseph, et al.</p> <p>2 791 Handwritten demonstrative by 136 3 plaintiff's counsel</p> <p>4 792 Handwritten demonstrative by 136 5 plaintiff's counsel</p> <p>6 794 Counsel demonstrative of 421 7 genetics, acetaminophen and 8 ADHD</p> <p>9 (Exhibits attached to the deposition.) 10 CERTIFICATE.....483 11 ACKNOWLEDGMENT OF DEPONENT.....485 12 ERRATA.....486 13 LAWYER'S NOTES.....487</p> | <p>1 DIRECT EXAMINATION</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Good morning, sir.</p> <p>4 Can you describe for the jury</p> <p>5 what the term "neurodevelopment" means?</p> <p>6 A. Neurodevelopment refers to the</p> <p>7 time period in life when the brain is</p> <p>8 developing.</p> <p>9 Q. Is neurodevelopment the process</p> <p>10 of developing the normal functions of the</p> <p>11 brain?</p> <p>12 A. Yes.</p> <p>13 (Faraone Exhibit 716 marked for</p> <p>14 identification.)</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. I'm going to mark as</p> <p>17 Exhibit 716 a chart, and I'll place that in</p> <p>18 front of the --</p> <p>19 A. Am I supposed to take that?</p> <p>20 Q. -- jury.</p> <p>21 MS. BROWN: I'll help you.</p> <p>22 I'll help you. Let's get a copy.</p> <p>23 MR. DOVEL: Place that in front</p> <p>24 of witness.</p> <p>25 THE WITNESS: Yep, okay.</p> |
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| <p>1 VIDEOGRAPHER: We are now on</p> <p>2 the record. My name is Danny Ortega,</p> <p>3 and I'm the legal videographer for</p> <p>4 Golkow Litigation Services.</p> <p>5 Today's date is September 7,</p> <p>6 2023, and the time is 8:34 a.m. --</p> <p>7 sorry, 8:35 a.m.</p> <p>8 This video deposition is being</p> <p>9 held at 395 Ninth Avenue, New York,</p> <p>10 New York, in the matter of</p> <p>11 Acetaminophen (Tylenol) ASD/ADHD</p> <p>12 Products Liability Litigation MDL.</p> <p>13 The deponent today is Stephen</p> <p>14 Faraone.</p> <p>15 All counsel will be noted on</p> <p>16 stenographic record.</p> <p>17 The court reporter is today is</p> <p>18 Carrie Campbell and will now swear in</p> <p>19 the witness.</p> <p>20</p> <p>21 STEPHEN V. FARAONE, Ph.D.,</p> <p>22 of lawful age, having been first duly sworn</p> <p>23 to tell the truth, the whole truth and</p> <p>24 nothing but the truth, deposes and says on</p> <p>25 behalf of the Plaintiffs, as follows:</p> | <p>1 MS. BROWN: And I'll object to</p> <p>2 Exhibit 716 as lacking foundation.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. Now, sir, the -- does the</p> <p>5 process of neurodevelopment include</p> <p>6 proliferation?</p> <p>7 MS. BROWN: Objection to the</p> <p>8 form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. What does proliferation refer</p> <p>12 to?</p> <p>13 A. Well, as you have it here in</p> <p>14 the diagram, as we all know, we start out as</p> <p>15 a single cell that divides, and each cell</p> <p>16 becomes specialized during that process of</p> <p>17 cell division. It's programmed into our DNA</p> <p>18 essentially how different cells will end up</p> <p>19 developing.</p> <p>20 The cells that are meant to</p> <p>21 form the brain are -- got them here as</p> <p>22 neuronal progenitors. They will further</p> <p>23 divide and differentiate into specialty</p> <p>24 cells.</p> <p>25 The loss during this process,</p> |

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| <p>1 the brain, as you know, has many, many, many 2 interconnections, so there are special 3 molecules that guide this -- the dendrites. 4 Think of -- think of neuron as 5 a -- essentially a cell body and it's 6 corrected -- that's connected to other 7 neurons that talk to each other by chemicals. 8 The connections that connect 9 those have to be determined by development -- 10 neurodevelopment, and this is the process of 11 proliferation. 12 Migration means cells are 13 moving to different parts of the brain, so 14 they're in the right place because there -- 15 different parts of the brain specialize in 16 different functions. 17 Q. Thank you. 18 Now, you mentioned 19 neuroprogenitors. 20 Are neuroprogenitors developed 21 from neural stem cells? 22 A. So there's -- there are 23 different ways -- you're talking about in the 24 brain as -- 25 Q. Yes.</p> | <p>1 MR. DOVEL: You're going to 2 have to reduce your comments down to 3 "objection to form," please. 4 MS. BROWN: Okay. But in order 5 to know if I should object to form, 6 I'm wondering if it has a source that 7 you could identify for the record. 8 QUESTIONS BY MR. DOVEL: 9 Q. I need an answer, sir. 10 MS. BROWN: Okay. I'll object 11 to form because I don't know the 12 source of this 716. 13 MR. DOVEL: Okay. Limit it to 14 "objection, form." 15 MS. BROWN: Sure. I just 16 needed to know that piece of 17 information to be able to make that 18 objection. 19 THE WITNESS: I'm sorry, you 20 have to repeat the question, please. 21 QUESTIONS BY MR. DOVEL: 22 Q. Sure. 23 During the normal process of 24 neurodevelopment, do all of the steps that 25 appear here on Exhibit 716 occur?</p> |
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| <p>1 A. The -- I think you might be 2 stressing my knowledge of basic biology, but 3 essentially there are -- the neural -- 4 there's a sequence of development, let's say, 5 that I just described, where you start with 6 cells, single cells, that divide that become 7 differentiated eventually -- well, that 8 migrate and become differentiated. 9 And this process is occurring 10 simultaneously, not necessarily sequentially, 11 and they differentiate the different -- the 12 different types of neurons. 13 You have a few of them listed 14 here that I'm not sure that the sequence here 15 is exactly correct, but all of these 16 activities occur during the process of the 17 brain developing into, we hope, a normal or 18 neurotypical brain as opposed to one that is 19 a diseased brain or disordered brain. 20 Q. Do all of the activities 21 depicted on 716 occur during the process of 22 the normal development of the brain? 23 MS. BROWN: And, Counsel, just 24 for the record, does 716 have a 25 source?</p> | <p>1 MS. BROWN: Objection to the 2 form and to the document. 3 THE WITNESS: Yeah. These 4 processes should all occur during the 5 normal process of neurodevelopment. 6 They will also occur during 7 the, if you will -- the process of 8 neurodevelopment that goes awry, but 9 they won't occur in the way that we 10 would hope they would to develop a 11 neurotypical or normal brain. 12 QUESTIONS BY MR. DOVEL: 13 Q. Does proliferation refer to the 14 process of increasing the number of cells? 15 MS. BROWN: Objection to the 16 form. Vague. 17 THE WITNESS: Yes, I've -- the 18 term is used in that way, yes. 19 QUESTIONS BY MR. DOVEL: 20 Q. When we talk about neuronal 21 proliferation, we're talking about creating 22 more cells? 23 MS. BROWN: Same objection. 24 THE WITNESS: So, as you know, 25 just to -- there's a little bit of</p> |

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| <p>1 background. I'm here as an expert in 2 ADHD. I'm not a neurobiologist, so I 3 can't tell you exactly how the term 4 "proliferation" might be used by a 5 neurobiologist that developed this 6 particular diagram. 7 But I can tell you that as 8 the -- as the brain develops, it's 9 necessary, obviously to create more 10 cells so that a full brain can be 11 grown, and that's -- that is part of 12 the process of normal neurotypical 13 brain development. 14 QUESTIONS BY MR. DOVEL: 15 Q. Does part of the process of 16 brain development include migrations, that is 17 where neurons move from one part to another 18 in the brain? 19 MS. BROWN: Objection to the 20 form of the question. 21 THE WITNESS: Yes, that's 22 correct. 23 QUESTIONS BY MR. DOVEL: 24 Q. Do neurons -- withdrawn. 25 During the process of</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. That would include dopaminergic 3 neuron, noradrenergic neurons, GABAergic 4 neurons and so on, right? 5 MS. BROWN: Same objection. 6 THE WITNESS: Yes, these are 7 examples of neurons that are -- 8 that are involved in the brain. 9 QUESTIONS BY MR. DOVEL: 10 Q. And during normal -- withdrawn. 11 And during brain development, 12 does that include the process of neurite 13 outgrowth? 14 MS. BROWN: Objection to the 15 form of the question. 16 THE WITNESS: Yes. 17 QUESTIONS BY MR. DOVEL: 18 Q. Neurite outgrowth refers to the 19 process of growing those little branches off 20 the dendrites and off the axon that the 21 neuron uses to connect with other neurons. 22 MS. BROWN: Same object -- 23 QUESTIONS BY MR. DOVEL: 24 Q. Is that right? 25 MS. BROWN: Sorry. Same</p> |
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| <p>1 neurodevelopment, do we have differentiation 2 of neurons? 3 MS. BROWN: Objection to the 4 form. Vague. 5 THE WITNESS: Yes, that's 6 correct. There are many different 7 types of cells in the brain, and in 8 order to have a normal functioning 9 brain, you would need to have 10 different types of neurons. 11 And also -- we also have to 12 mention glial cells, which are part 13 of -- well, you have them here, 14 actually. Okay. Glial progenitors, 15 yes, as well. 16 QUESTIONS BY MR. DOVEL: 17 Q. Now, when we talk about 18 differentiation, on 716 there are a number of 19 types of neurons that are listed. 20 Are these some of the neurons 21 that are developed during the process of 22 differentiation? 23 A. Yes. 24 MS. BROWN: Objection to the 25 form.</p> | <p>1 objection. 2 THE WITNESS: Yes. Yes. 3 MS. BROWN: Just give me one 4 second -- 5 THE WITNESS: Oh, I'm -- 6 MS. BROWN: -- if I need to 7 object, and then you'll answer. 8 No problem. 9 THE WITNESS: Okay. Sir? 10 QUESTIONS BY MR. DOVEL: 11 Q. Another process that occurs 12 during brain development is synapse 13 formation, right? 14 A. Yes, that is correct. Synapses 15 are a space between neurons whereby -- the 16 chemical message crosses the synapse to 17 communicate from one neuron to the next. 18 Q. In other words, the neurons 19 don't communicate through a direct electrical 20 connection; it's actually a chemical 21 connection across a small space? 22 MS. BROWN: I object to the 23 form of that question. 24 THE WITNESS: Yes. It's a 25 chemical connection, yes.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. The one neuron that's</p> <p>3 communicating with the other is going to send</p> <p>4 some chemical messengers over the space to</p> <p>5 the other neuron?</p> <p>6 A. Correct.</p> <p>7 Q. And those chemical messengers</p> <p>8 that are sent across, we call those</p> <p>9 neurotransmitters?</p> <p>10 A. Yes, neurotransmitters.</p> <p>11 Q. Neurotransmitters include</p> <p>12 things like dopamine, GABA, glutamate,</p> <p>13 noradrenaline, serotonin?</p> <p>14 A. Correct.</p> <p>15 Q. Now, glutamate, is that a major</p> <p>16 excitatory transmitter in the brain?</p> <p>17 MS. BROWN: Objection to the</p> <p>18 form of the question.</p> <p>19 THE WITNESS: I believe it is.</p> <p>20 I'm not 100 percent certain of that.</p> <p>21 I would have to check, but that's</p> <p>22 correct.</p> <p>23 QUESTIONS BY MR. DOVEL:</p> <p>24 Q. In other words, the --</p> <p>25 withdrawn.</p> | <p>1 sorry. Okay.</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question as well as beyond</p> <p>4 the scope of the expert report.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. Now, there's a group of</p> <p>7 neurotransmitters that are referred to as</p> <p>8 catecholamines; is that right?</p> <p>9 MS. BROWN: Same objections.</p> <p>10 THE WITNESS: That is -- that</p> <p>11 is correct.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. And those include dopamine and</p> <p>14 noradrenaline?</p> <p>15 MS. BROWN: Objection to the</p> <p>16 form.</p> <p>17 THE WITNESS: That's correct,</p> <p>18 noradrenaline is also referred to as</p> <p>19 norepinephrine, yes, sir.</p> <p>20 QUESTIONS BY MR. DOVEL:</p> <p>21 Q. Is dopamine involved in</p> <p>22 functions such as locomotion and motional and</p> <p>23 emotive behaviors?</p> <p>24 MS. BROWN: Objection to the</p> <p>25 form of the question.</p> |
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| <p>1 The different neurotransmitters</p> <p>2 perform different functions within the brain,</p> <p>3 right?</p> <p>4 MS. BROWN: Objection to the</p> <p>5 form. Beyond the scope.</p> <p>6 THE WITNESS: The different --</p> <p>7 yeah, the different neurotransmitters</p> <p>8 are -- yeah, sorry, the</p> <p>9 different neurotransmit -- well, the</p> <p>10 neurons that use different</p> <p>11 neurotransmitters are also located in</p> <p>12 different parts of the brain.</p> <p>13 Some of them are close to each</p> <p>14 other. Some of them are further</p> <p>15 apart, and they have different</p> <p>16 functions.</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. The GABAergic neurons, the ones</p> <p>19 that use GABA as a transmitter, they're</p> <p>20 involved in inhibiting -- inhibitory</p> <p>21 functions in the brain; is that right?</p> <p>22 A. I believe that's --</p> <p>23 MS. BROWN: Same -- hold on.</p> <p>24 Hold on.</p> <p>25 THE WITNESS: Oh, yeah, I'm</p> | <p>1 THE WITNESS: Dopamine is</p> <p>2 involved in those behaviors.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. Now, when we talk about</p> <p>5 neurodevelopment, it takes place -- it</p> <p>6 started in the fetus in the first trimester,</p> <p>7 right?</p> <p>8 MS. BROWN: I object to the</p> <p>9 form of the question. Beyond the</p> <p>10 scope.</p> <p>11 THE WITNESS: Well, it's --</p> <p>12 yeah. Well, yes, it starts in the</p> <p>13 first trimester, yes.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. It continues in the second and</p> <p>16 third trimesters?</p> <p>17 MS. BROWN: Same objection to</p> <p>18 this line of questioning.</p> <p>19 THE WITNESS: It does continue</p> <p>20 in the second and third trimesters and</p> <p>21 even continues after the baby is born.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. By the time we're into the</p> <p>24 second and third trimesters, all of the</p> <p>25 processes that are identified in 716 are</p> |

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| <p>1 underway, right?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question. Calling for</p> <p>4 speculation.</p> <p>5 THE WITNESS: I don't know the</p> <p>6 exact timing of all of these, but I</p> <p>7 think we can say that during the fetal</p> <p>8 period, all of these -- all of these</p> <p>9 activities are -- all of these</p> <p>10 functions are occurring to help with</p> <p>11 the development of the brain.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. Before the baby is born,</p> <p>14 synapse formation is already underway, right?</p> <p>15 MS. BROWN: Same objection to</p> <p>16 form. Beyond the scope. Speculation.</p> <p>17 THE WITNESS: I'm sorry, the</p> <p>18 question was about synapse formation</p> <p>19 is underway, yes, before the baby the</p> <p>20 born.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. If a baby's brain is exposed to</p> <p>23 a toxicant in the fetal period, that toxicant</p> <p>24 could disrupt any one of these processes</p> <p>25 identified in 716, right?</p> | <p>1 MS. BROWN: Object to the form</p> <p>2 of the question. Well beyond the</p> <p>3 scope of his report.</p> <p>4 THE WITNESS: Okay. Okay. So</p> <p>5 I'm -- you said -- you used the word</p> <p>6 "fragile," and by fragile, I'm not --</p> <p>7 what do you mean by "fragile"?</p> <p>8 QUESTIONS BY MR. DOVEL:</p> <p>9 Q. Let me take that out of it and</p> <p>10 ask you a different question. It's a fair</p> <p>11 point.</p> <p>12 A. Yeah.</p> <p>13 Q. During -- withdrawn.</p> <p>14 We know in -- withdrawn.</p> <p>15 Science has determined that</p> <p>16 during fetal development, chemical exposures</p> <p>17 could cause permanent brain injury at doses</p> <p>18 that would not harm adults?</p> <p>19 MS. BROWN: Objection. Lacks</p> <p>20 foundation. Beyond the scope.</p> <p>21 Speculation.</p> <p>22 THE WITNESS: Well, I -- as I</p> <p>23 said, I'm here as an expert in ADHD.</p> <p>24 I haven't reviewed -- I'm not a</p> <p>25 toxicologist. I have not reviewed</p> |
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| <p>1 MS. BROWN: Objection to the</p> <p>2 form. Beyond the scope. Speculation.</p> <p>3 THE WITNESS: Well, I mean, it</p> <p>4 depends on what the toxicant is, but</p> <p>5 in a hypothetical sense, a toxicant</p> <p>6 could affect any of these -- any of</p> <p>7 these functions.</p> <p>8 QUESTIONS BY MR. DOVEL:</p> <p>9 Q. During the fetal development --</p> <p>10 development, chemical exposure could cause a</p> <p>11 permanent brain injury in a person, right?</p> <p>12 MS. BROWN: I object to the</p> <p>13 form of the question. Speculation.</p> <p>14 Incomplete hypothetical.</p> <p>15 THE WITNESS: It -- it's --</p> <p>16 it's a very reasonable hypothesis.</p> <p>17 It's possible that a given toxicant</p> <p>18 could affect these -- any of these</p> <p>19 functions.</p> <p>20 QUESTIONS BY MR. DOVEL:</p> <p>21 Q. And we know in science because</p> <p>22 the developing brain is so fragile, a</p> <p>23 chemical exposure could cause</p> <p>24 neurodevelopmental disease in a fetus even at</p> <p>25 doses that would not harm an adult, right?</p> | <p>1 that literature regarding whether any</p> <p>2 specific toxicants cause permanent --</p> <p>3 it's certainly reasonable to think</p> <p>4 that that would happen.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. What does etiology mean?</p> <p>7 MS. BROWN: Objection. Vague.</p> <p>8 THE WITNESS: That's the --</p> <p>9 when we talk about the etiology of</p> <p>10 disorder, we're talking about its</p> <p>11 causes.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. And what does pathogenesis</p> <p>14 mean?</p> <p>15 MS. BROWN: Same objection.</p> <p>16 THE WITNESS: Pathogenesis is</p> <p>17 essentially what happens between the</p> <p>18 etiological events and disorder.</p> <p>19 There's a series of events that occur</p> <p>20 that change some system in the body.</p> <p>21 If we're talking about</p> <p>22 neurodevelopment, that changes the</p> <p>23 brain in a way that makes it different</p> <p>24 from the neurotypical brain that we</p> <p>25 would hypothesize or maybe one day</p> |

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| <p>1 actually document caused the disorder. 2 QUESTIONS BY MR. DOVEL: 3 Q. Is pathogenesis the manner in 4 which a disease develops? 5 MS. BROWN: Object to the form 6 of the question. 7 THE WITNESS: I guess I 8 would -- I mean, I'd guess I prefer to 9 phrase it the way I phrased it. It -- 10 it's the series of events that occur 11 in the organ of interest here, we're 12 talking about the brain, that explain 13 the symptoms of the disorder and the 14 onset -- and the onset of the 15 disorder. 16 QUESTIONS BY MR. DOVEL: 17 Q. Is pathophysiology the set of 18 disordered physiological processes that are 19 associated with a disease? 20 MS. BROWN: Objection. Scope. 21 Speculation. I object to the form of 22 the question. 23 THE WITNESS: That's fair. 24 QUESTIONS BY MR. DOVEL: 25 Q. Does pathophysiology include</p> | <p>1 THE WITNESS: So in the process 2 of normal cellular activity, right, 3 they're talking about the level of a 4 single cell, cells -- cells produce 5 what are called reactive oxygen 6 species or ROS. These reactive oxygen 7 species are toxic to the cells, so the 8 cell has to have mechanisms for 9 eliminating them. And they do. I 10 mean, it's a normal process of the 11 activities of a cell that is reactive 12 oxygen species. These reactive oxygen 13 species are produced and they're 14 eliminated. 15 If the reactive oxygen species 16 reach a level that is too high to be 17 removed quick -- sufficiently quickly, 18 then the cell will experience 19 oxidative stress. If that gets out of 20 control, the cell would -- could 21 experience apoptosis, which is just 22 cell death, which, obviously, is not 23 good for the cell or for the organ 24 that the cell participates in. 25 And sometimes that can occur</p> |
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| <p>1 both the cause and the development of the 2 disease? 3 MS. BROWN: Objection to the 4 form. Vague. 5 THE WITNESS: Well, I don't use 6 the term "pathophysiology" to refer to 7 causes. Some people may, but... 8 QUESTIONS BY MR. DOVEL: 9 Q. How do you use the term 10 "pathophysiology"? 11 MS. BROWN: Objection. 12 Foundation. 13 THE WITNESS: I use it to refer 14 to the series of events that occur 15 between the etiological events that 16 are the -- if you will, the causes of 17 the condition, and then the events 18 that occur in the organ or organs of 19 interest, in this case we're talking 20 about the brain, and then, of course, 21 lead to the disorder. 22 QUESTIONS BY MR. DOVEL: 23 Q. What is oxidative stress? 24 MS. BROWN: Objection to the 25 form. Beyond the scope.</p> | <p>1 without any notable injury if 2 oxidative stress is at low levels, but 3 if oxidative stress gets out of hand, 4 then you can have too much cell death 5 and problems can ensue. 6 QUESTIONS BY MR. DOVEL: 7 Q. During normal cellular 8 metabolism, do cells create these reactive 9 oxygen species? 10 MS. BROWN: I object to this 11 whole line of questioning as well 12 beyond the scope. 13 MR. DOVEL: Let's see. Now, 14 the Court entered an order saying the 15 following: "Any attorney making a 16 form objection shall state the 17 objection as 'objection to form' and 18 make no other statement." 19 Were you aware of that? 20 MS. BROWN: Counsel, can I see 21 the entire document, please? 22 MR. DOVEL: Were you aware of 23 that? 24 MS. BROWN: Yes. I'm making a 25 form objection and telling you why so</p> |

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| <p>1 you have the opportunity to correct 2 the question. 3 MR. DOVEL: Then when you chose 4 to say more, that was an intentional 5 violation of the Court's order, wasn't 6 it? 7 MS. BROWN: No, Counsel, and 8 you are intentionally questioning this 9 witness on areas well beyond the scope 10 of his report. It is entirely 11 improper, and it is unfair. You are 12 asking him questions about opinions he 13 did not give in a report in this case, 14 and I object. 15 MR. DOVEL: Are you going to 16 obey the Court's order or not? 17 MS. BROWN: Of course I am. 18 QUESTIONS BY MR. DOVEL: 19 Q. And, sir, are -- 20 MS. BROWN: And I would ask 21 counsel that you -- he is being put up 22 as a witness on his report, and I 23 would ask that you properly tailor 24 your questions to the substance of his 25 report.</p> | <p>1 QUESTIONS BY M. DOVEL: 2 Q. If these free radicals, as you 3 say, get out of hand, can they cause damage 4 in the body? 5 A. Yes, they can cause damage to 6 cell -- individual cells, which, of course, 7 if you damage too many individual cells, then 8 the organ itself becomes damaged. 9 Q. Does the body have mechanisms 10 to defend itself from radicals and reactive 11 oxygen species? 12 A. I -- 13 MS. BROWN: Hold on. 14 I object to the form of the 15 question. 16 THE WITNESS: I'm sorry, could 17 you repeat that again? 18 QUESTIONS BY MR. DOVEL: 19 Q. Yeah. 20 Does the body have mechanisms 21 to deal with free radicals and reactive 22 oxygen species? 23 A. Yes, as a normal -- is that me? 24 Oh, I apologize. I thought I put that on do 25 not disturb.</p> |
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| <p>1 MR. DOVEL: Are you going to 2 limit your remarks to "objection, 3 form," or should we call the Court? 4 MS. BROWN: Are you going to 5 limit the questions to the substance 6 of his report? That's what he's here 7 to talk about, and you've put a 8 document that you wouldn't even tell 9 me the foundation for in front of him, 10 and you're asking him a series of 11 questions -- 12 MR. DOVEL: I'm going to get 13 extra time because you're taking my 14 time commenting when you should be 15 quiet. 16 MS. BROWN: You don't have to 17 yell at me and speak rudely. Please 18 tailor your questions to what he's 19 being tendered for. 20 QUESTIONS BY MR. DOVEL: 21 Q. Doctor, are reactive oxygen 22 species sometimes referred to as free 23 radicals? 24 MS. BROWN: Same objection. 25 THE WITNESS: That is correct.</p> | <p>1 MS. BROWN: If it's something 2 you need to take, Doctor -- 3 THE WITNESS: No, no, no. 4 Well, it's probably my grandchild 5 being born, but I can find out later. 6 MR. WATTS: Congrats. 7 MS. BROWN: Do you -- hold on. 8 Can we go off the record for 9 one second? 10 THE WITNESS: It's okay. 11 That's fine. That's fine. 12 MS. BROWN: Hold on. Hold on. 13 Hold on. 14 Can we just take five seconds, 15 Counsel, to see if his grandson or 16 grandchild was -- 17 THE WITNESS: It's fine. 18 Let's -- I'd rather continue with 19 this. 20 MS. BROWN: Okay. We'll take a 21 break in an hour. 22 THE WITNESS: I have two 23 already, so it's -- 24 MS. BROWN: Okay. We will -- 25 let's get through -- let's get through</p> |

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| <p>1 a little more questioning, and let's</p> <p>2 let you just check in --</p> <p>3 THE WITNESS: I might get in</p> <p>4 trouble, but --</p> <p>5 MS. BROWN: Okay. All right.</p> <p>6 I'm sure counsel will allow you to</p> <p>7 check in with the birth of your</p> <p>8 grandchild.</p> <p>9 THE WITNESS: No, no, that's</p> <p>10 fine. We can wait for the break. My</p> <p>11 mind is on -- we're in a nice groove</p> <p>12 here about oxidative stress, so I</p> <p>13 don't -- I want to continue with that.</p> <p>14 And I'm sorry, I have to ask</p> <p>15 you to repeat that question.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. Sure.</p> <p>18 Does the body have mechanisms</p> <p>19 to defend itself from oxidative stress?</p> <p>20 MS. BROWN: Objection to the</p> <p>21 form of the question.</p> <p>22 THE WITNESS: So as a normal</p> <p>23 part of the cell's functioning, it</p> <p>24 must remove the free radicals from the</p> <p>25 cell, or inactivate them, so that the</p> | <p>1 in the body?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: You're getting</p> <p>5 way out of my wheelhouse here now.</p> <p>6 Just so we all know for sure, I'm not</p> <p>7 a physician. I'm a psychologist, so</p> <p>8 details about inflammation are not</p> <p>9 something I've ever studied or</p> <p>10 considered myself an expert in.</p> <p>11 QUESTIONS BY MR. DOVEL:</p> <p>12 Q. Well, we're not going to go</p> <p>13 into details. Let's just talk about at a</p> <p>14 general level and what you do know.</p> <p>15 Do you understand that</p> <p>16 inflammation is a process of generating an</p> <p>17 immune response in the body?</p> <p>18 MS. BROWN: Objection to the</p> <p>19 form of the question.</p> <p>20 THE WITNESS: Yeah, I'd really</p> <p>21 rather not talk about inflammation and</p> <p>22 details about immune response, if</p> <p>23 that's okay with you.</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. It's not.</p> |
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| <p>1 cell survives, yes.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Does the cell defend itself</p> <p>4 with something called antioxidants?</p> <p>5 MS. BROWN: Objection to the</p> <p>6 form of the question.</p> <p>7 THE WITNESS: Yes.</p> <p>8 QUESTIONS BY MR. DOVEL:</p> <p>9 Q. If the antioxidants are</p> <p>10 insufficient to deal with the effects of the</p> <p>11 radicals, then does oxidative stress occur?</p> <p>12 MS. BROWN: Objection to the</p> <p>13 form of the question.</p> <p>14 THE WITNESS: That's correct.</p> <p>15 If the oxidative load of the cell</p> <p>16 exceeds what the antioxidants and the</p> <p>17 inactivation -- other methods of</p> <p>18 inactivation, I believe there may be</p> <p>19 others besides antioxidants, then,</p> <p>20 yes, the cell -- the cell experiences</p> <p>21 oxidative stress which could destroy</p> <p>22 the cell.</p> <p>23 QUESTIONS BY MR. DOVEL:</p> <p>24 Q. Is inflammation the process of</p> <p>25 generating an immune response to fight germs</p> | <p>1 A. It's not. Okay.</p> <p>2 Q. I'd like to get your response.</p> <p>3 A. Okay.</p> <p>4 MS. BROWN: Whoa. No. No.</p> <p>5 No. No. Hold on. Hold on.</p> <p>6 He will ask a question, and you</p> <p>7 will answer the question --</p> <p>8 MR. DOVEL: Limit your</p> <p>9 comments.</p> <p>10 THE WITNESS: Right.</p> <p>11 MS. BROWN: -- and let's just</p> <p>12 proceed like that. If you don't know</p> <p>13 the answer, you can tell him that.</p> <p>14 THE WITNESS: Okay.</p> <p>15 Well, my understanding of</p> <p>16 inflammation is that if we experience</p> <p>17 an event in our bodies that is</p> <p>18 attacking normal functioning, one of</p> <p>19 the responses is inflammation. And</p> <p>20 that can be a good thing. It can --</p> <p>21 it can bring appropriate molecules to</p> <p>22 the site of whatever the event is.</p> <p>23 I'm not sure if it's only</p> <p>24 immune events. Other events can</p> <p>25 occur, I believe -- and, again, I'm</p> |

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| <p>1 not an expert in the causes of 2 inflammation. And this is, again, a 3 positive thing when inflammation 4 happens. But if inflammation gets out 5 of hand, it can be a problem. 6 QUESTIONS BY MR. DOVEL: 7 Q. Does inflammation induce 8 reactive oxygen species to occur? 9 MS. BROWN: Objection to the 10 form of the question. 11 THE WITNESS: That, I don't 12 know. 13 QUESTIONS BY MR. DOVEL: 14 Q. Have you ever seen any 15 information associating inflammation with 16 oxidative stress? 17 MS. BROWN: Objection to the 18 form of the question. 19 THE WITNESS: You know, I may 20 have. I have read so much stuff in 21 the last 30 years, I just don't 22 recall. 23 QUESTIONS BY MR. DOVEL: 24 Q. What are interleukins? 25 MS. BROWN: Objection to the</p> | <p>1 form of the question. 2 If you understand it and know 3 it -- 4 THE WITNESS: I do understand 5 that cytokines are signaling 6 molecules, and I believe it's correct 7 that interleukins are part of that 8 group. 9 QUESTIONS BY MR. DOVEL: 10 Q. Does the human inflammatory 11 response depend on these interleukins to 12 regulate it? 13 MS. BROWN: I object to the 14 form of the question. 15 THE WITNESS: Again, that's -- 16 I don't -- I just don't know. 17 QUESTIONS BY MR. DOVEL: 18 Q. Is it common to abbreviate the 19 names of different interleukins with a 20 number, such as IL2, IL3, IL6 and so on? 21 MS. BROWN: Objection -- 22 THE WITNESS: That, I do 23 know -- oh, sorry. 24 MS. BROWN: Just give me one 25 second to object.</p> |
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| <p>1 form. 2 THE WITNESS: Well, 3 interleukins -- you're going to have 4 me guessing here a bit on this one. 5 MS. BROWN: Nobody wants you to 6 guess. If you know the answer, we 7 want you to give it. If you don't, 8 nobody wants you to guess. 9 QUESTIONS BY MR. DOVEL: 10 Q. Let me withdraw and give you a 11 different question. 12 Are interleukins a group of 13 cytokines? 14 MS. BROWN: Objection to the 15 form of the question. 16 MR. DOVEL: Let me just finish 17 my question. 18 MS. BROWN: Sorry, Counsel, I 19 thought you did. 20 QUESTIONS BY MR. DOVEL: 21 Q. Are interleukins a group of 22 cytokines that are -- that is, these are 23 proteins that are used as signaling 24 molecules? 25 MS. BROWN: I object to the</p> | <p>1 THE WITNESS: I'm new to this 2 whole process, so I -- 3 MS. BROWN: It's okay. It's 4 okay. No problem at all. 5 THE WITNESS: It's -- I will -- 6 I apologize. 7 Whose turn is it? 8 QUESTIONS BY MR. DOVEL: 9 Q. It's your turn. 10 A. My turn? Okay. 11 Questions about numbers. Yes, 12 I'm familiar with, you know, IL number -- a 13 certain number to refer to different 14 molecules. 15 Q. Different interleukins. 16 A. Different interleukins, yes. 17 Yeah. 18 Q. These interleukins, signaling 19 molecules, they can either bring inflammation 20 up or bring it down, right? 21 MS. BROWN: Objection to the 22 form of the question. 23 THE WITNESS: I'm going to say 24 I don't know again. I'm not certain 25 enough to say "yes" or "no" to that.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Now, ADHD is a disease that's</p> <p>3 diagnosed based upon symptoms, right?</p> <p>4 MS. BROWN: Objection to the</p> <p>5 form.</p> <p>6 THE WITNESS: It -- yes, it's</p> <p>7 based upon 18 symptoms specified in</p> <p>8 the Diagnostic and Statistical Manual</p> <p>9 of the American Psychiatric</p> <p>10 Association, or International</p> <p>11 Classification of Diseases.</p> <p>12 Also, there is a -- the only --</p> <p>13 I think the only other system is the</p> <p>14 Chinese diagnostic system, but they're</p> <p>15 all -- they are all very similar to</p> <p>16 one another.</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. One set of symptoms that can be</p> <p>19 diagnosed as ADHD would be inattentive</p> <p>20 symptoms; that is, symptoms of inattention,</p> <p>21 right?</p> <p>22 A. That's correct. The DSM lists</p> <p>23 nine symptoms of inattention. If you have</p> <p>24 six or more and you're a child, you can be</p> <p>25 diagnosed with ADHD.</p> | <p>1 and impulsivity.</p> <p>2 But they're also triggers in</p> <p>3 the environment, typically</p> <p>4 psychosocial triggers. A child is</p> <p>5 placed in a certain environment and</p> <p>6 they're going to be more hyperactive</p> <p>7 and not in other environments.</p> <p>8 Well, for example, the classic</p> <p>9 example is a child plays a video game</p> <p>10 and they -- you know, they're able to</p> <p>11 attend to the video game, they're able</p> <p>12 to sit still for maybe an hour or so.</p> <p>13 And sometimes a parent will say,</p> <p>14 "Well, I don't think my child has ADHD</p> <p>15 because they can sit and do video</p> <p>16 games."</p> <p>17 The symptoms are</p> <p>18 context-dependent because they -- it</p> <p>19 depends what's happening in the</p> <p>20 environment -- in the environment.</p> <p>21 And so the reason why it's</p> <p>22 important that a trained professional</p> <p>23 make the diagnosis is they can</p> <p>24 differentiate when it's sensible that</p> <p>25 the symptoms occur and don't occur.</p> |
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| <p>1 If you have five or more and</p> <p>2 you're an adolescent or a -- I'm sorry,</p> <p>3 you're an older adolescent, I think the</p> <p>4 cutoff is 17, or an adult, then you can be</p> <p>5 diagnosed with ADHD.</p> <p>6 Q. Another set of symptoms that</p> <p>7 could lead to an ADHD diagnosis is</p> <p>8 hyperactive-impulsive symptoms, right?</p> <p>9 A. That is correct. And again,</p> <p>10 there are nine symptoms in the similar</p> <p>11 diagnostic thresholds.</p> <p>12 Q. Now, these symptoms of ADHD,</p> <p>13 either inattention or</p> <p>14 hyperactivity-impulsivity, those are caused</p> <p>15 by the brain, right?</p> <p>16 MS. BROWN: Objection to the</p> <p>17 form.</p> <p>18 THE WITNESS: So the reason I'm</p> <p>19 pausing here is because it's a little</p> <p>20 more complicated than that.</p> <p>21 So the -- we believe that there</p> <p>22 is pathophysiology in the brain that</p> <p>23 makes a person -- a child in this</p> <p>24 case -- prone to experiencing these</p> <p>25 symptoms: Inattention, hyperactivity</p> | <p>1 Just because a child is able to -- for</p> <p>2 example, some kids are able to -- with</p> <p>3 ADHD will be able to sit still in</p> <p>4 novel environments because there's a</p> <p>5 natural inhibition that occurs in</p> <p>6 novel environments. So when they get</p> <p>7 to the doctor's office, they're not as</p> <p>8 hyperactive and impulsive or</p> <p>9 inattentive as they might be in</p> <p>10 other -- in other environments.</p> <p>11 And so the diagnostician takes</p> <p>12 that into account when they're making</p> <p>13 the diagnosis.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Are there differences in the</p> <p>16 brains of folks diagnosed with ADHD as</p> <p>17 compared to folks who do not have ADHD?</p> <p>18 MS. BROWN: Objection. Form.</p> <p>19 THE WITNESS: So there's --</p> <p>20 there is a large neuroimaging</p> <p>21 literature. I think the most</p> <p>22 well-defined brain differences between</p> <p>23 people with and without ADHD come from</p> <p>24 the INMA consortium studies, of which</p> <p>25 I was a participant. And for clarity,</p> |

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| <p>1 I'm not a neuro imager, but I was 2 involved in the process of collecting 3 neuroimaging data on ADHD when I 4 was -- worked at the master in Harvard 5 at Harvard Medical School. 6 So I'm part of this consortium, 7 and so I know the data, and I'm on 8 their publications. 9 What they have shown is that 10 there are -- when you look across -- 11 with the INMA consortium did is they 12 basically collected structural 13 neuroimaging data from sites around 14 the world that it would agree to 15 participate, and most of the sites 16 doing ADHD work agreed to participate. 17 And so they had several thousand 18 scans, cases and controls. So it's 19 the biggest imaging study ever. 20 And in two papers published by 21 Martine Hoogman, those papers document 22 small but statistically significant 23 differences in the brains of children 24 with ADHD compared to not. But we 25 didn't -- we couldn't document those</p> | <p>1 significant on their own, they were 2 consistent with the data that we show 3 in children. 4 And how it was done is very 5 complicated, so I don't think you want 6 to hear. And I'll stop there, unless 7 you're interested in that point. 8 QUESTIONS BY MR. DOVEL: 9 Q. What I want to just be clear on 10 is, is it the case that science has concluded 11 that ADHD is a disorder of the brain, or is 12 it a disorder of some other part of the body? 13 MS. BROWN: Objection to the 14 form of the question. 15 THE WITNESS: So, actually, I'm 16 going to answer your question, but I 17 realized I forgot to answer the other 18 question completely. 19 So I told you about the INMA 20 structural imaging data, but there are 21 other kinds of imaging in the imaging 22 world. You can image the functioning 23 of the brain, the function of the 24 magnetic resonance imaging. You 25 can -- there's been a lot of work done</p> |
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| <p>1 same changes in adolescents or adults. 2 Now, a few things need to be 3 said about that to fully understand 4 it. One of -- one is that 5 differences -- these neuroimaging 6 differences are small. It's not the 7 kind of difference that a radiologist 8 would pick up in a brain scan and say, 9 ah, this person has ADHD because of 10 their brain scan, which they might 11 do -- which they would do if somebody 12 suffers traumatic brain injury, they 13 can see very clearly the brain was 14 affected. 15 The second is that I had 16 published some data using some of the 17 more advanced -- well, I should back 18 up. 19 So the Hoogman paper is -- used 20 sort of standard statistical analysis 21 to do their work. I applied some 22 machine-learning methods to the same 23 dataset and was able to show that even 24 though the findings in the adult 25 dataset were not statistically</p> | <p>1 in what's called the resting state 2 network of the brain. That work is, 3 at this point, equivocal. It's not as 4 persuasive as the INMA work because 5 you've got a bunch of small studies 6 that don't completely agree with one 7 another. 8 But there are some -- I 9 won't get -- we can't get into the 10 details here, but I do want you to 11 know other studies exists. 12 There's another very intriguing 13 body of literature about the dopamine 14 transporter, which has been of much 15 interest in the ADHD world because the 16 dopamine transport is the main site 17 action of two medications that are 18 helpful for people with ADHD. That's 19 methylphenidate and amphetamine. 20 People typically know those as Ritalin 21 and Adderall, but there are many 22 different types of those drugs. 23 So because of that, a number of 24 sites, a number of people around the 25 country, have looked at -- there's an</p> |

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| <p>1 imaging technology that is actually 2 pretty impressive. You can actually 3 image the amount of dopamine 4 transporters in the brain. 5 And these studies -- most of 6 these studies show that there are 7 excess dopamine transporters in the 8 brains of people with ADHD. And 9 that -- and they suggest that the -- 10 if you will, that the density or the 11 amount of these transporters declines 12 with age, which is kind of interesting 13 because there is an age-dependent 14 decline in ADHD. For some people 15 symptoms go away with age. 16 This is all very intriguing 17 data. The problems with it is that 18 there are -- the samples have to be 19 small because this is done with 20 positron emission tomography. It can 21 only be done in adults because you 22 don't do these studies in children 23 because it exposes them to radiation. 24 But the most -- the most 25 interesting data partly because of</p> | <p>1 THE WITNESS: So to reboot that 2 point was about the -- I think I was 3 just about ending up my comments on 4 the dopamine transporter that the 5 studies were intriguing because of 6 small samples. In some studies that 7 are not completely in agreement with 8 that, there's some discussion in the 9 literature about that. 10 So, actually, that was the end 11 of my comments there. I'm sorry. 12 I'll have to ask you to repeat the 13 question that motivated me to answer 14 the prior question. 15 QUESTIONS BY MR. DOVEL: 16 Q. Is ADHD a disorder of the 17 brain? 18 A. That's right. You'd asked me 19 if science believes that, and I would say 20 that most experts that -- in the ADHD field 21 would agree with that locus of -- the locus 22 of the pathophysiology is the brain. 23 Q. Is it the case that ADHD is a 24 neurodevelopmental disease? That is, a 25 development -- its pathogenesis occurs during</p> |
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| <p>1 connected -- 2 MR. DOVEL: I have 3 to interrupt. I think we've wandered 4 away from my question at this point. 5 THE WITNESS: Okay. Well -- 6 MS. BROWN: No, no, no, no. 7 Hold on. 8 You can finish your answer, and 9 then counsel can ask a follow-up 10 question. We can't -- you can't cut 11 him off. 12 THE WITNESS: Okay. I'm being 13 too professorial perhaps. 14 QUESTIONS BY MR. DOVEL: 15 Q. Well, do you remember my 16 question? 17 A. Well, what I was trying to do 18 was complete the answer to the prior 19 question, because I realized I hadn't given 20 you a complete answer. 21 You were asking about the -- 22 MS. BROWN: Please finish -- go 23 ahead and finish your answer, and 24 counsel will follow up if he has a 25 follow-up.</p> | <p>1 the development of the brain? 2 MS. BROWN: Objection to the 3 form of the question. 4 THE WITNESS: So it's defined 5 in the DSM, the diagnostic manual that 6 we use from the American Psychiatric 7 Association, that manual defines 8 several neurodevelopmental disorders. 9 And they're defined as 10 neurodevelopment because it's believed 11 that their pathogenesis occurs during 12 the development of the brain, which, 13 again, we have to keep in mind that 14 the brain is developing. It's -- a 15 very important time is the fetal 16 period, but brain development 17 continues up until some people are now 18 saying between up to age 20, 25, 30 19 the brain development continues. 20 And so events that occur later 21 in life can also have an effect on 22 brain development. 23 But the classification of ADHD 24 or intellectual disability, or 25 stuttering, all of these</p> |

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| <p>1 neurodevelopmental disorders as</p> <p>2 neurodevelopmental doesn't mean that</p> <p>3 we know the causes or the</p> <p>4 pathophysiology.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. Is it the case that the risk</p> <p>7 factors identified to date are primarily</p> <p>8 genetic or environmental exposures during</p> <p>9 fetal development?</p> <p>10 A. So to answer that question, I</p> <p>11 would have to first talk about the word --</p> <p>12 the words "risk factors" because they're used</p> <p>13 differently in science and in the real world,</p> <p>14 so to speak.</p> <p>15 The risk factor, the way I use</p> <p>16 it and the way it's -- my understanding is</p> <p>17 it's defined in epidemiology is the same as</p> <p>18 saying it's a correlate. It's something</p> <p>19 that's correlated with ADHD but not known to</p> <p>20 be a causal agent.</p> <p>21 The problem with the phrase</p> <p>22 "risk factor," it can sound like it's causal</p> <p>23 but it actually doesn't mean it.</p> <p>24 So having said that -- and I</p> <p>25 will use the word "correlate" in the same way</p> | <p>1 causes of ADHD.</p> <p>2 Q. Is it true that the risk</p> <p>3 factors identified to date are primarily</p> <p>4 genetic or environmental exposures during</p> <p>5 fetal development?</p> <p>6 A. That's right. You asked about</p> <p>7 fetal development.</p> <p>8 So certainly many of the --</p> <p>9 many of the environmental causes -- many of</p> <p>10 the environmental correlates or risk factors</p> <p>11 are people have studied the area of fetal</p> <p>12 development as the window of interest.</p> <p>13 People have also looked at, for</p> <p>14 example, I think I talk about extreme</p> <p>15 deprivation in orphanages, traumatic brain</p> <p>16 injury, as these are, of course, post-fetal</p> <p>17 events that occur. People have also studied</p> <p>18 stress in the family environment and the</p> <p>19 degree to which that affects the onset of</p> <p>20 ADHD.</p> <p>21 But, yes, there is a large</p> <p>22 number of studies, body of literature, that</p> <p>23 focuses on the fetal development period.</p> <p>24 Q. Do you agree, sir, that the</p> <p>25 risk factors identified to date are primarily</p> |
| Page 62 | Page 64 |
| <p>1 that you're using the word "risk factor."</p> <p>2 There are -- we know from --</p> <p>3 well, you asked about genes and environment.</p> <p>4 So it's -- we know from the very large</p> <p>5 database of genetic studies stretching back</p> <p>6 from the original family, twin and adoption</p> <p>7 studies that go back to '80s, maybe somewhere</p> <p>8 even I think in the '70s or earlier, that</p> <p>9 ADHD has a sizeable genetic component,</p> <p>10 heritability about 76 percent.</p> <p>11 I was -- I had the good fortune</p> <p>12 to move my career in the direction of</p> <p>13 genetics back in the '90s, and I helped lead</p> <p>14 an international consortium to discover the</p> <p>15 first genome-wide significant loci for ADHD</p> <p>16 which are -- we believe to be causal for</p> <p>17 other disorder.</p> <p>18 So we clearly have evidence for</p> <p>19 genes being causal in ADHD -- genes or</p> <p>20 genomic loci, more technically, being causal</p> <p>21 in ADHD.</p> <p>22 There have been a number of</p> <p>23 environmental factors that have been studied</p> <p>24 and are -- I would classify as correlates of</p> <p>25 ADHD that have not yet been shown to be</p> | <p>1 genetic or environmental exposures during</p> <p>2 fetal development?</p> <p>3 A. Oh, wow. Good question.</p> <p>4 What I don't know is -- yeah, I</p> <p>5 guess I would have to say I would agree</p> <p>6 that -- well, the genetics for sure. There's</p> <p>7 no question about that.</p> <p>8 When we look at environmental</p> <p>9 correlates of ADHD that have been studied, I</p> <p>10 think it's fair to say they mostly occur in</p> <p>11 the fetal development period. Yeah.</p> <p>12 Q. As a result, is it reasonable</p> <p>13 to conclude that the brains -- the brains of</p> <p>14 patients with ADHD had some disruption or</p> <p>15 dysregulation during fetal development?</p> <p>16 MS. BROWN: Objection to the</p> <p>17 form.</p> <p>18 THE WITNESS: I, and personally</p> <p>19 as a scientist, think that's a very</p> <p>20 good hypothesis; that -- from a person</p> <p>21 who studies genomics, I think what's</p> <p>22 happening is that the -- from the --</p> <p>23 from the genomic's side, I think that</p> <p>24 the genes that are ultimately -- or I</p> <p>25 would say the genetic variants that</p> |

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| <p>1 ultimately are causal, in the causal 2 pathway, are changing the brain in a 3 way to make it atypical that promotes 4 a person's susceptibility to 5 developing ADHD. 6 So if we have -- if we were to 7 finally come up with a set of 8 environmental causes that we could say 9 are documented and agreed upon, it's 10 likely that they could play a role in 11 that same process. So it's a very 12 reasonable hypothesis, which, of 13 course, is why people are looking -- 14 are looking in that area. 15 QUESTIONS BY MR. DOVEL: 16 Q. When we talk about inattention 17 or hyperactivity, it's systems in the brain 18 that regulate that activity, right? 19 MS. BROWN: Objection to the 20 form. 21 THE WITNESS: So it's 22 an inter -- it's an interaction 23 between the systems in the brain that 24 are not -- that are atypical with the 25 environmental context that the child</p> | <p>1 are -- they are raised in environments 2 that has a lot of external regulation. 3 We call it scaffolding. Parents, for 4 example, schools, provide a lot of 5 external supports, and so their ADHD 6 symptoms are -- become dormant, and 7 they don't emerge until the child 8 moves into an environment that 9 requires more self-regulation. 10 So you can see sometimes the 11 emergence of ADHD when a child goes 12 from elementary school to middle 13 school or middle school to high 14 school. Particularly leaving the 15 family home, going from high school to 16 take a job or going to college, all of 17 a sudden that requires massive 18 self-regulation, and sometimes that's 19 when the symptoms will begin to 20 emerge. 21 They may have been noticeable 22 at a lower level or earlier in life. 23 So -- 24 QUESTIONS BY MR. DOVEL: 25 Q. Do you remember my question,</p> |
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| <p>1 happens to be in. And it's -- I -- 2 when I lecture on ADHD, I'll talk 3 about the -- it's ADHD merges when the 4 challenges of -- the challenges to the 5 brain of self-regulation from the 6 environment exceeds the ability of the 7 brain to regulate itself. 8 So we can think of ADHD some 9 ways as a disorder of self-regulation. 10 Normal development means that -- we 11 all know this as we develop from -- we 12 expect that, you know, a 2-year-old is 13 going to -- I have one right now in my 14 life, a grandchild, that they're going 15 to run around and they're going to 16 climb on furniture and they're going 17 to do all these things because they 18 haven't developed -- their brain 19 hasn't developed the capacity of 20 self-regulation. As they get older, 21 that capacity develops. 22 Now, some children, and we see 23 this -- I've seen this when I was in 24 clinical practice and it's documented 25 in research, there are some kids that</p> | <p>1 sir? 2 A. I do. 3 MS. BROWN: Hold on. Hold on. 4 Wait. Please. 5 THE WITNESS: Okay. Wait. 6 MS. BROWN: Counsel, you 7 interrupted him. He has to be able to 8 finish his answer. 9 Please finish, and then counsel 10 will follow up. 11 THE WITNESS: Okay. Now, I am 12 really trying to answer -- because you 13 asked me if it's the brain, and what 14 I'm saying is that the brain has a 15 role, but the environmental context 16 also has a role. 17 QUESTIONS BY MR. DOVEL: 18 Q. We'll get to that. The 19 brain -- I'm talking about the brain's part. 20 MS. BROWN: Counsel, you 21 interrupted him for a second time. 22 Wait, please, Doctor. 23 THE WITNESS: I'm sorry. 24 MS. BROWN: Hold on. I just 25 want to make sure we have a clean</p> |

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| <p>1 record, and the only way that is going 2 to happen is if counsel allows you to 3 finish, you finish, and then he 4 follows up. Okay? 5 THE WITNESS: I apologize. 6 MS. BROWN: No. No. There's 7 no apology necessary. He interrupted 8 you. 9 Finish your answer. 10 And then, Counsel, can we take 11 a quick break, please? 12 Wait. Hold -- is that okay, 13 sir? 14 MR. DOVEL: Let's get an answer 15 to the question. 16 MS. BROWN: That's what I just 17 said. If you look at the realtime, 18 finish your answer and then could we 19 take a quick break, please. 20 Go ahead. 21 THE WITNESS: Okay. Can you 22 ask me the question again? It's -- 23 I've got -- 24 QUESTIONS BY MR. DOVEL: 25 Q. Are there systems in the brain</p> | <p>1 THE WITNESS: So here's where 2 it gets a little murkier, but we would 3 say that dopamine and noradrenaline 4 are primary regulators. But, yes, 5 GABA and glutamate appear to be 6 involved as well. 7 It's also the nicotinic -- 8 there's also a nicotinic system in the 9 brain that regulates dopamine neurons, 10 so it can play a role in that as well. 11 MR. DOVEL: All right. Let's 12 go off the record. 13 MS. BROWN: Thank you. Let's 14 take a quick break, and then we'll 15 come back. Why don't we -- 16 VIDEOGRAPHER: I'm sorry. The 17 time right now is 9:22 a.m., and we're 18 off the record. 19 (Off the record at 9:22 a.m.) 20 VIDEOGRAPHER: The time right 21 now is 9:30 a.m. We're back on the 22 record. 23 QUESTIONS BY MR. DOVEL: 24 Q. Does dysregulation of the 25 dopamine system play a role in ADHD?</p> |
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| <p>1 that regulate activity and hyperactivity? 2 MS. BROWN: Objection to the 3 form. 4 THE WITNESS: Yes. 5 QUESTIONS BY MR. DOVEL: 6 Q. Are there systems in the brain 7 that regulate attention and focus? 8 MS. BROWN: Same objection. 9 THE WITNESS: Yes. 10 QUESTIONS BY MR. DOVEL: 11 Q. Do the brain systems that 12 control activity, hyperactivity, attention 13 and focus make use of neurotransmitters? 14 MS. BROWN: Objection to the 15 form. 16 THE WITNESS: Yes, they do. 17 QUESTIONS BY MR. DOVEL: 18 Q. Do those include dopamine and 19 noradrenaline and norepinephrine? 20 MS. BROWN: Same objection. 21 THE WITNESS: That's correct. 22 QUESTIONS BY MR. DOVEL: 23 Q. Do those include GABA and 24 glutamate? 25 MS. BROWN: Same objection.</p> | <p>1 MS. BROWN: Objection to the 2 form. 3 THE WITNESS: It's one of the 4 leading hypothesis, yes. 5 QUESTIONS BY MR. DOVEL: 6 Q. Is it supported by reliable 7 scientific evidence? 8 A. It's supported by two main 9 sources of evidence. One is the 10 pharmacology -- the neuropsychopharmacology 11 of the drugs and the mechanism of action of 12 the drugs, although that's a little backwards 13 because we're saying that the drugs are 14 telling us about the -- what's going on in 15 the brain, but it's not unreasonable to do 16 that. 17 And it's also supported 18 somewhat by the studies I told you before 19 about imaging and dopamine transporter. 20 That, of course, is -- I'm sorry, you asked 21 about dopamine. I'll stop right there. 22 Q. This hypothesis that the 23 dopamine system is involved is -- withdrawn. 24 Is it the case that there's 25 something that happens during</p> |

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| <p>1 neurodevelopment that results in changes in 2 the dopamine system that would cause ADHD? 3 MS. BROWN: Objection to form. 4 THE WITNESS: That's a leading 5 hypothesis. 6 I would add to that that part 7 of that hypothesis is involved in the 8 neurogenic system because for the same 9 reasons we believe there are drugs -- 10 there's a class of drugs that treats 11 ADHD that works in the neurogenic 12 system, and that's one of -- one of 13 the reasons why there's a hypothesis 14 about both neurogenic system and the 15 dopamine neurogenic system. 16 QUESTIONS BY MR. DOVEL: 17 Q. And is there reasonable 18 scientific evidence for both of those parts, 19 the dopamine system and the neurogenic 20 system? 21 MS. BROWN: Objection to the 22 form. 23 THE WITNESS: I suppose I need 24 to know what you mean by reasonable 25 scientific evidence.</p> | <p>1 Q. Is there reliable -- well, take 2 out the word "reasonable." Withdrawn. Let 3 me give you a different question. 4 Is there reliable scientific 5 evidence that changes in the dopamine system 6 can cause ADHD? 7 MS. BROWN: Objection to the 8 form. 9 THE WITNESS: That's where 10 we -- the only -- well, of course 11 it's very difficult to examine the 12 dopamine system in the living brain, 13 and the only way that it -- as far as 14 I know -- and again, I'm not an expert 15 in all of these technologies. 16 But the only way I know of that 17 one can interrogate the dopamine 18 system in the brain is by -- before I 19 talked to you about the imaging 20 studies of the dopamine transporter. 21 And those studies have been -- 22 when I look at those studies, I see 23 them as promising studies that 24 implicate the dopamine transporter 25 and -- as an important protein in the</p> |
| Page 74 | Page 76 |
| <p>1 It's -- I would say there's 2 enough -- there's enough evidence for 3 me to say that they're leading 4 hypotheses about what's happening in 5 the brain, but it seems -- well, I 6 would also think that other -- we know 7 from the genomic studies, for example, 8 that were implicating -- some of the 9 genes were implicating are outside of 10 dopamine system. 11 QUESTIONS BY MR. DOVEL: 12 Q. Is it the case that it's 13 believed that there are a number of different 14 biological pathways that could lead to ADHD? 15 A. Well, we know that there are 16 different pathways in the sense the most 17 obvious one is a traumatic brain injury, and 18 you get ADHD. That's likely a different 19 pathway than having a high genomic load for 20 ADHD. 21 Q. And there's -- it's believed to 22 be there's a variety of different biological 23 pathways, right? 24 A. That is a leading hypothesis, 25 you know.</p> | <p>1 brain that's involved in ADHD. Other 2 people would argue that, no, the 3 studies are too inconsistent with 4 that. 5 So there's -- I still think -- 6 I still think it's a reasonable 7 hypothesis, and I think other 8 colleagues would agree with that. 9 QUESTIONS BY MR. DOVEL: 10 Q. Is the hypothesis supported by 11 reliable scientific evidence? 12 MS. BROWN: Objection to the 13 form of the question. 14 THE WITNESS: Well, in -- the 15 way I use the term "reliable," it's -- 16 kind of means repeatable. If you 17 repeat the same experiment, you get 18 the same results. 19 And the problem with the 20 dopamine transporter data is that the 21 same result hasn't always been 22 repeated in -- and the sample sizes 23 are small, it's -- by necessity 24 because these are very expensive 25 studies using positron emission</p> |

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| <p>1 tomography.</p> <p>2 And they can only be done in</p> <p>3 adults, which is -- another problem</p> <p>4 with the imaging studies is that we</p> <p>5 can't always separate out the effects</p> <p>6 of a disorder on the brain from the</p> <p>7 effects on the causes on the brain.</p> <p>8 That's a limitation to inference,</p> <p>9 so...</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. All right. Well, let me take</p> <p>12 out the word "reliable" then.</p> <p>13 Is there any scientific</p> <p>14 evidence that changes in the dopamine system</p> <p>15 during neurodevelopment plays a role in</p> <p>16 causing some ADHD?</p> <p>17 MS. BROWN: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: The scientific</p> <p>20 evidence would be the studies -- the</p> <p>21 imaging studies of the dopamine</p> <p>22 transporter and what we know about</p> <p>23 the mechanism of action of drugs that</p> <p>24 work -- that are helpful for --</p> <p>25 they're not curative, but they're</p> | <p>1 he has a complete copy, so we just</p> <p>2 don't know.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. You recognize this as a portion</p> <p>5 of the slide deck that you created on the</p> <p>6 overview of attention-deficit/hyperactivity</p> <p>7 disorder?</p> <p>8 A. I do.</p> <p>9 Q. There's a section that --</p> <p>10 labeled pathophysiology of ADHD, right?</p> <p>11 A. That's correct.</p> <p>12 Q. And in that section, if you</p> <p>13 turn to the next page, one of the slides</p> <p>14 says, "The medicines that treat ADHD work in</p> <p>15 the pathways implicated by neuroimaging</p> <p>16 studies."</p> <p>17 Right?</p> <p>18 A. Yes, that's -- that is correct.</p> <p>19 Q. And that's the noradrenergic</p> <p>20 and dopaminergic pathways?</p> <p>21 A. That is correct.</p> <p>22 (Faraone Exhibit 778 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. I'm going to mark as</p> |
| Page 78 | Page 80 |
| <p>1 helpful for ADHD.</p> <p>2 (Faraone Exhibit 771 marked for</p> <p>3 identification.)</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. I'm going to mark as</p> <p>6 Exhibit 771 a partial of the overview</p> <p>7 presentation.</p> <p>8 MS. BROWN: Counsel, do you</p> <p>9 have a copy, a complete copy?</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. I want to turn to page --</p> <p>12 MS. BROWN: I'm sorry, do I</p> <p>13 have a --</p> <p>14 MR. DOVEL: I'm not going to</p> <p>15 respond to your question. Just hand</p> <p>16 him the document. It's my turn to ask</p> <p>17 him questions.</p> <p>18 MS. BROWN: Okay.</p> <p>19 MR. DOVEL: You'll have a</p> <p>20 chance at the end of the day.</p> <p>21 MS. BROWN: But you're giving</p> <p>22 him a partial document.</p> <p>23 I object to this document as</p> <p>24 being incomplete, and counsel doesn't</p> <p>25 seem to want to answer my question if</p> | <p>1 Exhibit 778 the Primer.</p> <p>2 Sir, you recognize this as the</p> <p>3 ADHD Primer that you authored?</p> <p>4 A. Yes.</p> <p>5 Q. I would like to -- and this was</p> <p>6 in 2015 this came out?</p> <p>7 A. Correct.</p> <p>8 Q. Let's turn to page 7. In the</p> <p>9 left column, the sentence 3 -- let's see.</p> <p>10 Actually, let's go to paragraph 2. It's not</p> <p>11 highlighted. Go down to sentence 3.</p> <p>12 A. Where does it start? Let me</p> <p>13 just take a look --</p> <p>14 Q. It starts with "a meta-analysis</p> <p>15 of peripheral biomarkers."</p> <p>16 A. Let me take a look. Hold on a</p> <p>17 second here.</p> <p>18 MS. BROWN: Counsel, on page 1?</p> <p>19 MR. DOVEL: Page 7.</p> <p>20 THE WITNESS: Page 7. He's</p> <p>21 talking about this here. Let me see.</p> <p>22 Hold on.</p> <p>23 Okay. Yeah, I see the sentence</p> <p>24 you're referring to.</p> <p>25</p> |

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| <p style="text-align: right;">Page 81</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. You identify some results, and</p> <p>3 you say, "The results support the idea that</p> <p>4 the catecholaminergic neurotransmitter</p> <p>5 systems and the hypothalamic pituitary</p> <p>6 adrenal axis are dysregulated in ADHD."</p> <p>7 Right?</p> <p>8 A. That's correct, yes.</p> <p>9 Q. And then there's some clinical</p> <p>10 studies that implicate other systems,</p> <p>11 including the serotonergic, glutamatergic,</p> <p>12 nicotinic and neurite outgrowth systems,</p> <p>13 right?</p> <p>14 A. Yes.</p> <p>15 Q. There's scientific evidence</p> <p>16 supporting dysregulation of those systems,</p> <p>17 right?</p> <p>18 A. Yes. Of course this is in</p> <p>19 2015. The field's moved on a bit, and we're</p> <p>20 actually revising this paper this year, and</p> <p>21 I'm not sure that the HPA axis will stay --</p> <p>22 will stay in. We're still -- it's still</p> <p>23 in -- under discussion, but in 2015 this was</p> <p>24 the state of the science.</p> <p>25 Q. Sir, have you testified in a</p> | <p style="text-align: right;">Page 83</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. No. No.</p> <p>3 A. Colloquial sense.</p> <p>4 Q. Colloquial.</p> <p>5 Some experts, they come with a</p> <p>6 different approach. They are paid to reach</p> <p>7 certain conclusions, and the testimony and</p> <p>8 opinions that they provide are only</p> <p>9 supportive of that opinion. They are acting</p> <p>10 as paid testifiers, as advocates.</p> <p>11 You understand that that may be</p> <p>12 the case?</p> <p>13 A. I --</p> <p>14 MS. BROWN: I object -- hold</p> <p>15 on. I object to the form of the</p> <p>16 question.</p> <p>17 THE WITNESS: I understand</p> <p>18 that, what you're saying there.</p> <p>19 QUESTIONS BY MR. DOVEL:</p> <p>20 Q. Now, let's talk about some of</p> <p>21 the ways that we can tell whether we're</p> <p>22 dealing with a truth seeker or a paid</p> <p>23 testifier.</p> <p>24 A truth seeker is going to be</p> <p>25 someone that takes account of all of the</p> |
| <p style="text-align: right;">Page 82</p> <p>1 deposition before today?</p> <p>2 A. No, this is my first.</p> <p>3 Q. Can I have the ELMO?</p> <p>4 Now, sir, you understand that</p> <p>5 expert witnesses are sometimes called in</p> <p>6 legal cases?</p> <p>7 A. I do.</p> <p>8 Q. And that's your role here?</p> <p>9 A. (Witness nods head.)</p> <p>10 Q. Yes?</p> <p>11 A. I do understand that, yes.</p> <p>12 Q. Now, some -- you may not have a</p> <p>13 lot of familiarity with expert witnesses, but</p> <p>14 some of them, they come to the job as truth</p> <p>15 seekers, as people trying to find the truth.</p> <p>16 You understand what that means?</p> <p>17 MS. BROWN: Objection -- I</p> <p>18 object to the form of the question and</p> <p>19 to the document you're creating on the</p> <p>20 screen.</p> <p>21 THE WITNESS: I think I</p> <p>22 understand the colloquial sense of the</p> <p>23 truth seeker. I assume it doesn't</p> <p>24 have a special legal meaning.</p> <p>25</p> | <p style="text-align: right;">Page 84</p> <p>1 facts and evidence no matter which side it</p> <p>2 helps, right?</p> <p>3 MS. BROWN: Object to the form.</p> <p>4 Object to the line of the questioning.</p> <p>5 Object to the document on the screen,</p> <p>6 that you've created, I assume.</p> <p>7 THE WITNESS: I'm sorry, the</p> <p>8 question was?</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. A truth seeker would be someone</p> <p>11 that takes account of all facts and evidence</p> <p>12 no matter which side it helps or hurts?</p> <p>13 MS. BROWN: Same objection.</p> <p>14 THE WITNESS: That sounds right</p> <p>15 to me.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. It's part of the scientific</p> <p>18 process, right?</p> <p>19 A. That's what we do.</p> <p>20 Q. Now, somebody who is a paid</p> <p>21 testifier, they'd be willing to ignore facts</p> <p>22 and evidence that help the other side, right?</p> <p>23 MS. BROWN: Objection to the</p> <p>24 form --</p> <p>25 THE WITNESS: So --</p> |

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| <p>1 MS. BROWN: -- of the question. 2 THE WITNESS: Okay. So I know 3 a lot about the scientific process. I 4 don't know much about this other side, 5 what you're calling the advocate or 6 the paid testifier. 7 So I'm happy to have you 8 educate me, but I don't know -- I 9 don't -- I don't have answers to that. 10 I haven't studied that. I don't know 11 what -- if people have done studies of 12 paid testifiers and what they do or 13 don't do. 14 MS. BROWN: Counsel is not here 15 to educate you. He'll just ask you a 16 question. 17 THE WITNESS: Oh, okay. Right, 18 right. Okay. Right, right, right. 19 MS. BROWN: If you know it, 20 you'll answer, and if you don't, 21 you'll tell him that. That's okay. 22 QUESTIONS BY MR. DOVEL: 23 Q. Would you agree, sir, that if 24 the jury sees someone that ignores facts and 25 evidence that help the other side, that would</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Just a second. 3 Will you answer my next 4 question because I want to get it on the 5 record before you answer it? 6 A. I -- 7 MS. BROWN: Wait. Hold on. It 8 was not clear to me that he was 9 finished with the prior answer. Let's 10 just try not to interrupt the witness, 11 please, Counsel, so we can have a 12 clean record. 13 QUESTIONS BY MR. DOVEL: 14 Q. Let's talk about something else 15 that relates to truth seeking versus paid 16 testifier. 17 Would you agree, sir, that a 18 truth seeker is not going to exaggerate 19 helpful facts? 20 MS. BROWN: I object to the 21 form of the question and to the 22 demonstrative. 23 THE WITNESS: So I -- you know, 24 I just -- I'm not here as an expert 25 and truth seeker and a paid testifier,</p> |
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| <p>1 indicate they're not acting as a truth 2 seeker? 3 MS. BROWN: I object to the 4 form of the question. 5 THE WITNESS: I -- well, I 6 would think that a jury is going to 7 have their interpretation of whether 8 an expert is or is not ignoring 9 something, and I don't even understand 10 how that process works. 11 So it's somebody who's -- 12 somebody who is ignoring a body of 13 evidence. Like, let's say, for 14 example, there's, you know, a bunch of 15 sibling control studies that don't 16 agree with Gustavson, and I totally 17 ignored them, you know, that would be 18 a bad thing, and one shouldn't do 19 that. 20 QUESTIONS BY MR. DOVEL: 21 Q. Why is it a -- 22 MS. BROWN: Wait. Wait. He 23 wasn't done. Please finish. 24 THE WITNESS: Well, it's a bad 25 thing because --</p> | <p>1 so I just -- you know, I don't -- we 2 can -- if you want to talk to me about 3 what we do in science, I can -- I can 4 talk to you about that, but that's -- 5 QUESTIONS BY MR. DOVEL: 6 Q. Well, you understand -- 7 MS. BROWN: He's not done, sir. 8 THE WITNESS: I mean, that's -- 9 MS. BROWN: Please let him 10 finish. 11 THE WITNESS: That's the extent 12 of what I know. But, you know, I -- 13 you know, I don't know what 14 paid testify -- I mean, you're saying 15 paid testifiers. I don't know that 16 all paid testifiers do these things, 17 right. 18 QUESTIONS BY MR. DOVEL: 19 Q. Do you understand, sir, that 20 exaggerating, it's the process of -- 21 withdrawn. 22 MS. BROWN: Hold on. Hold on. 23 There's no question. Let him ask the 24 question -- 25 THE WITNESS: Well, I --</p> |

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| <p>1 MS. BROWN: And then you'll 2 answer it. 3 THE WITNESS: I think I need to 4 say something kind of -- it is, I 5 think, responsive to your question, 6 okay? 7 And that is -- it's sort of the 8 premise of the question, right? 9 So the graphic we have here is 10 implying that all paid testifiers 11 ignore facts and evidence and 12 exaggerate and overstate the helpful 13 facts. 14 And I can't agree with that. 15 It's -- yeah. 16 QUESTIONS BY MR. DOVEL: 17 Q. Now, would you agree, sir, that 18 this would be one symptom of a paid 19 testifier? One thing we could look to -- 20 A. I would not agree with that, 21 no. Absolutely not. 22 I mean, sir, I am a paid 23 testifier. I'm being paid by the attorneys 24 to be an expert in the area of ADHD, and I -- 25 I'm not somebody who ignores facts and</p> | <p>1 MS. BROWN: Objection to the 2 form of the question. 3 THE WITNESS: I haven't looked 4 up the definition of exaggeration. 5 I -- I'm not here to be an expert in 6 what words mean or don't mean in some 7 technical, legal sense. 8 QUESTIONS BY MR. DOVEL: 9 Q. Not technical, legal sense. 10 Your own understanding, sir. 11 Is exaggerating a form of 12 deception? 13 MS. BROWN: Objection to the 14 form of the question. Oy. 15 THE WITNESS: Is exaggerating a 16 form -- I don't -- no, I don't think I 17 can agree with that because if -- 18 exaggeration would mean that a person 19 is -- for example, you know, people 20 write articles. They review the 21 literature. They write their own 22 articles, and then they discuss what's 23 important to them as an individual. 24 And so they may exaggerate a 25 certain part of what they've done, and</p> |
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| <p>1 evidence. I don't exaggerate and overstate 2 helpful facts. 3 You may disagree with that, but 4 that's not my -- you know, I don't do that. 5 So I don't -- I can't -- I don't know that -- 6 I don't think it's -- to say all paid 7 testifiers are doing this does not seem -- 8 you know, I would have to guess that that's 9 inaccurate. 10 Q. Well, let's add on to this, to 11 be clear, that they're not a truth seeker. 12 MS. BROWN: I object, if that's 13 a question. 14 MR. DOVEL: So let me -- so let 15 me ask a question -- 16 MS. BROWN: And I object to the 17 document -- 18 MR. DOVEL: -- so then you can 19 object. 20 MS. BROWN: All right. 21 QUESTIONS BY MR. DOVEL: 22 Q. Now, sir, exaggeration is, for 23 example, when you describe something in 24 misleading terms that make it seem more 25 important than it really is?</p> | <p>1 they may have very good reasons for 2 doing that. 3 QUESTIONS BY MR. DOVEL: 4 Q. If someone -- 5 MS. BROWN: He's not done, 6 Counsel. 7 THE WITNESS: It's -- so you 8 can be a truth seeker, and you can -- 9 you can communicate to your 10 audience -- for example, typically we 11 do this in the discussion section of a 12 paper, these are -- I found a bunch of 13 things in this research. Here are the 14 things that are important to me. And 15 the discussion section frequently 16 takes that. It doesn't discuss every 17 item that one presented in the -- in 18 the results section. 19 And so that would fall under 20 the category of exaggeration. So I 21 don't think I can agree with -- I 22 mean, so sometimes -- not just 23 sometimes, I would say frequently 24 scientists will focus their discussion 25 on things that are important to them,</p> |

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| <p style="text-align: right;">Page 93</p> <p>1 which is a form of exaggeration. 2 QUESTIONS BY MR. DOVEL: 3 Q. If you describe something in 4 misleading terms that make it seem more 5 important or helpful than it really is, is 6 that a form of deception? 7 MS. BROWN: I object to the 8 form of the question. 9 THE WITNESS: Well, the 10 question seems to be if you're being 11 misleading, is that deception, and it 12 seems kind of circular, that if you're 13 misleading somebody intentionally, 14 you're, you know, leading them down 15 the garden path, so to speak, and 16 deceiving them. 17 QUESTIONS BY MR. DOVEL: 18 Q. Let's talk about another topic, 19 which is minimizing. 20 Would you agree, sir, that 21 someone who is a truth seeker is not going to 22 attempt to describe something in misleading 23 terms that make it seem less important and 24 minimize it? 25 MS. BROWN: I object to the</p> | <p style="text-align: right;">Page 95</p> <p>1 the side that hired the expert? 2 MS. BROWN: Object -- 3 QUESTIONS BY MR. DOVEL: 4 Q. In other words, you were hired 5 by folks representing Johnson & Johnson, 6 right? 7 MS. BROWN: Objection to the 8 form. 9 THE WITNESS: Yes, I was hired 10 by the defense attorneys here. Yes. 11 QUESTIONS BY MR. DOVEL: 12 Q. A fact that would be bad for 13 Johnson & Johnson would be what I would call 14 a bad fact; one would tend to undermine their 15 case and support ours. That's a bad fact. 16 Do you understand that? 17 A. I would -- 18 MS. BROWN: Hold on. 19 I object to the form of the 20 question and the demonstrative. 21 THE WITNESS: Okay. I 22 understand now what you mean by "a bad 23 fact." 24 QUESTIONS BY MR. DOVEL: 25 Q. Now, sir, would you agree that</p> |
| <p style="text-align: right;">Page 94</p> <p>1 form of the question, to the 2 demonstrative. 3 THE WITNESS: Well, first of 4 all, in the world of science, we're 5 not talk about -- so we don't -- we 6 don't talk about facts. We talk about 7 what does the evidence tell us from a 8 given study that we've conducted. 9 So I know this might seem like 10 a -- I'm parsing this too carefully, 11 but I understand, you know, sometimes 12 the use of facts is -- perhaps you 13 mean in the same sense I would mean 14 it; that I would, for example, do a 15 study, I would come up with some 16 results, and those results are the 17 facts of my -- of my -- of my work. 18 The statement you have there is 19 just very -- you know, like, for 20 example, what is a bad fact, what 21 is -- what do you mean by "a bad 22 fact"? 23 QUESTIONS BY MR. DOVEL: 24 Q. By a bad fact, I mean a fact 25 that does not help the side of the witness --</p> | <p style="text-align: right;">Page 96</p> <p>1 a truth seeker, an expert witness who came as 2 a truth seeker, is going to give direct 3 answers to questions and is not going to be 4 evasive? 5 MS. BROWN: I object to the 6 form of the question and the 7 demonstrative. 8 THE WITNESS: I would say it's 9 important that the -- I answer your 10 questions as truthfully and accurately 11 as possible. 12 QUESTIONS BY MR. DOVEL: 13 Q. If someone were to evade 14 answering questions, we could reasonably 15 infer that they know what the answer is but 16 that they don't want to say it, right? 17 MS. BROWN: Objection to the 18 form of the question. 19 THE WITNESS: I think that's a 20 bit too speculative for me to agree 21 with. I mean, there could be reasons 22 that somebody doesn't answer a 23 question that have nothing to do with 24 trying to hide something that they 25 don't want you to know.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. If somebody intentionally</p> <p>3 evades answering a question, is it reasonable</p> <p>4 to infer that they don't want to answer it?</p> <p>5 MS. BROWN: I object to the</p> <p>6 form of the question.</p> <p>7 THE WITNESS: So if we --</p> <p>8 you're saying if we knew that they</p> <p>9 intentionally are not answering a</p> <p>10 question, then if we -- if we had some</p> <p>11 way of knowing that there was their</p> <p>12 intention, then, yes, that would have</p> <p>13 been -- I mean, it's kind of a</p> <p>14 circular question, isn't it? That</p> <p>15 that would be their intention because</p> <p>16 we somehow know that, that they</p> <p>17 intended to do that.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Would you agree, sir, that a</p> <p>20 truth seeker is going to give straight</p> <p>21 answers whereas an expert witness that's not</p> <p>22 a truth seeker is going to give evasive and</p> <p>23 crooked answers?</p> <p>24 MS. BROWN: I object to the</p> <p>25 form of the question and to the</p> | <p>1 MS. BROWN: Objection to the</p> <p>2 form.</p> <p>3 THE WITNESS: Well, the overall</p> <p>4 methodology for deciding a question of</p> <p>5 causality is the Bradford Hill method</p> <p>6 of determining causality.</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. And that's the section that you</p> <p>9 addressed at the very end of your report,</p> <p>10 right?</p> <p>11 A. I believe it's summarized at</p> <p>12 the beginning, and then it's -- yes, it's at</p> <p>13 the very end of the report.</p> <p>14 Q. Let's turn to paragraph 7 of</p> <p>15 your report.</p> <p>16 A. Which one is that?</p> <p>17 Q. Paragraph 7.</p> <p>18 A. Oh, 7. Okay.</p> <p>19 Q. In your summary of opinions.</p> <p>20 A. 7.</p> <p>21 Q. In paragraph 7, you express a</p> <p>22 conclusion about the lack of reliable</p> <p>23 scientific evidence that acetaminophen causes</p> <p>24 ADHD.</p> <p>25 And you summarize it there in</p> |
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| <p>1 demonstrative --</p> <p>2 THE WITNESS: If by straight --</p> <p>3 MS. BROWN: -- that's on the</p> <p>4 screen.</p> <p>5 THE WITNESS: Well, I'm -- hold</p> <p>6 on. Yeah.</p> <p>7 MS. BROWN: Go ahead.</p> <p>8 THE WITNESS: If you -- if by</p> <p>9 "straight" you mean truthful and</p> <p>10 accurate to the best of my knowledge</p> <p>11 and -- yes, that's -- straight answers</p> <p>12 are very important.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. I'm done with the ELMO now.</p> <p>15 In your report, did you</p> <p>16 identify -- withdrawn.</p> <p>17 In your report, did you have a</p> <p>18 section where you laid out the methodology</p> <p>19 that you would be following?</p> <p>20 A. Okay. In the report I wouldn't</p> <p>21 say there's one specific section. The</p> <p>22 methodology is laid out throughout the entire</p> <p>23 report. We can go through that. Let's see.</p> <p>24 Q. What is the name of your</p> <p>25 methodology?</p> | <p>1 paragraph 7, right?</p> <p>2 A. Yes, I see that.</p> <p>3 Q. And this is an examination of</p> <p>4 the epidemiological studies and other</p> <p>5 evidence, right?</p> <p>6 A. That's correct.</p> <p>7 Q. What's the name of the</p> <p>8 methodology that you employed in order to</p> <p>9 analyze that evidence that's described in</p> <p>10 paragraph 7?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form.</p> <p>13 THE WITNESS: Well, I think I'm</p> <p>14 using the scientific method the way</p> <p>15 scientists think about causality and</p> <p>16 how I want to address causality, and</p> <p>17 I'm using Bradford Hill as the</p> <p>18 touchstone for how one looks at this</p> <p>19 type of epidemiologic data.</p> <p>20 And then in the report itself,</p> <p>21 I describe why I selected specific</p> <p>22 studies, why I didn't, and why I did</p> <p>23 and did not include some studies --</p> <p>24 some of the epidemiologic studies in</p> <p>25 that process.</p> |

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| <p style="text-align: right;">Page 101</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Well, sir, you reached the</p> <p>3 conclusion that the --</p> <p>4 MS. BROWN: Were you done?</p> <p>5 THE WITNESS: Well, of course I</p> <p>6 reviewed the literature, selected the</p> <p>7 studies based upon inclusion/exclusion</p> <p>8 criteria. I present those very</p> <p>9 transparently in the report. That --</p> <p>10 I mean, part of the methodology is</p> <p>11 being transparent which studies are we</p> <p>12 referring to. That's transparent.</p> <p>13 I'm very transparent in what I</p> <p>14 consider to be important features of</p> <p>15 the study that are guiding my opinion,</p> <p>16 and I focused on a confounding by</p> <p>17 indication and confoundings by</p> <p>18 genetics and maternal</p> <p>19 attention-deficit/hyperactivity</p> <p>20 disorder.</p> <p>21 So those -- those are the</p> <p>22 features of how I approached the</p> <p>23 methodology. It's all there in -- and</p> <p>24 we could go -- we could go paragraph</p> <p>25 by paragraph, if you like, and I</p> | <p style="text-align: right;">Page 103</p> <p>1 A. There's -- again, I would say</p> <p>2 I'm using the scientific methods, the way</p> <p>3 that scientists think about a body of</p> <p>4 literature. There's no -- there's no</p> <p>5 specific name that's attached to that.</p> <p>6 Q. Sir, is it your understanding</p> <p>7 that doctors of pregnant women, OB/GYNs, they</p> <p>8 overwhelming recommend taking acetaminophen</p> <p>9 for a woman who's got aches and pains or</p> <p>10 fever?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form.</p> <p>13 THE WITNESS: Again, I'm not a</p> <p>14 physician, so I don't know all the</p> <p>15 details about what physicians are</p> <p>16 supposed to or not supposed to do.</p> <p>17 That's -- yeah, that's outside -- it's</p> <p>18 well outside my area of expertise and</p> <p>19 the mandate for these proceedings</p> <p>20 here.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Do you understand that</p> <p>23 physicians regularly tell their patients that</p> <p>24 acetaminophen is safe?</p> <p>25 MS. BROWN: Objection to the</p> |
| <p style="text-align: right;">Page 102</p> <p>1 could -- I could show you those points</p> <p>2 in the report.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. Well, before you did your</p> <p>5 Bradford Hill analysis and used the Bradford</p> <p>6 Hill factors, you had already reached the</p> <p>7 conclusion that the epidemiological data did</p> <p>8 not support a finding of an association?</p> <p>9 A. Where are you?</p> <p>10 Q. Paragraph 8.</p> <p>11 A. Well, paragraph 8 is a summary.</p> <p>12 It's after the whole thing is done, the</p> <p>13 summary is written. So it's not -- what</p> <p>14 you're saying isn't actually -- is not</p> <p>15 accurate.</p> <p>16 Q. Well, sir, when you did your</p> <p>17 analysis of the epidemiology, did you mention</p> <p>18 Bradford Hill?</p> <p>19 A. No. Bradford Hill is only</p> <p>20 mentioned at the -- well, in the summary at</p> <p>21 the beginning and at the end of the report.</p> <p>22 Q. Okay. So when you did your</p> <p>23 epidemiology -- your analysis of the</p> <p>24 epidemiology, what's the name of the method</p> <p>25 that you used?</p> | <p style="text-align: right;">Page 104</p> <p>1 form of the question.</p> <p>2 THE WITNESS: So I honestly</p> <p>3 don't know what the -- I mean,</p> <p>4 physicians are a wide -- there's a</p> <p>5 wide range of physicians and a wide</p> <p>6 range of practice of physicians. I</p> <p>7 don't know what they do in their daily</p> <p>8 practice.</p> <p>9 I may know something about how</p> <p>10 they deal with ADHD, but I don't know</p> <p>11 how they deal with acetaminophen.</p> <p>12 And I do know in the ADHD</p> <p>13 world, there's a wide range of, you</p> <p>14 know, competence, expertise, in how</p> <p>15 they deal with ADHD, both from a</p> <p>16 diagnostic and a treatment part.</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. Do you understand that the</p> <p>19 organizations that -- of which OB/GYNs are a</p> <p>20 part of, such as ACOG, that they don't warn</p> <p>21 against taking acetaminophen?</p> <p>22 MS. BROWN: Objection to the</p> <p>23 form of the question.</p> <p>24 THE WITNESS: I have looked at</p> <p>25 some of the statements from</p> |

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| <p>1 professional associations with an eye 2 to finding out what they thought about 3 the question of causality, and they 4 don't -- they conclude that there's -- 5 the evidence doesn't support 6 causality. 7 But I have not looked and -- I 8 have not looked at them with an eye 9 towards getting an exact sense of what 10 their recommendations are for 11 physicians. 12 QUESTIONS BY MR. DOVEL: 13 Q. Do you understand that they, in 14 general, recommend against taking aspirin or 15 Advil or Aleve for pregnant women? 16 MS. BROWN: Objection to the 17 form of the question. 18 THE WITNESS: Okay. That -- I 19 do recognize that. I do understand 20 that -- again, to the best of my 21 recollection and understanding is that 22 they will recognize -- that 23 acetaminophen is recommended over 24 those, having read those reports and 25 so forth from the associations.</p> | <p>1 right? 2 MS. BROWN: Objection to the 3 form of the question. 4 THE WITNESS: That would -- 5 yes. 6 QUESTIONS BY MR. DOVEL: 7 Q. If a woman were to fully 8 consider the risks as explained to them by 9 the doctor involving Tylenol and aspirin, 10 they're more likely to take Tylenol than 11 aspirin, Advil or Aleve, right? 12 MS. BROWN: Objection to the 13 form of the question. 14 THE WITNESS: Hold on a second. 15 That's a long question. 16 If a woman -- could you repeat 17 the question, please? Thanks. 18 QUESTIONS BY MR. DOVEL: 19 Q. Yes. Let me just finish 20 writing this. 21 So I've added attentive to 22 doctor's recommendation with a checkmark 23 under Tylenol. 24 Do you see that? 25 MS. BROWN: I object to the</p> |
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| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. I'm going to use the ELMO 3 again. 4 If a doctor's giving advice to 5 pregnant women -- woman in general, they're 6 going to recommend Tylenol over aspirin, 7 Advil and Aleve, right? 8 MS. BROWN: Objection to the 9 creation of the document. 10 THE WITNESS: You're -- are we 11 talking here just about a hypothetical 12 average doctor whose -- 13 QUESTIONS BY MR. DOVEL: 14 Q. Yes. 15 A. We'll talk about a doctor 16 that's following, say, guidelines from some 17 professional association that recommends 18 that. 19 Q. Yes. 20 A. Then they very likely will 21 recommend Tylenol. 22 Q. If a pregnant woman is -- pays 23 attention to the doctor's recommendation, 24 like, wants to follow it, they're more likely 25 to take Tylenol than aspirin, Advil or Aleve,</p> | <p>1 creation of this lawyer document. 2 THE WITNESS: And the checkmark 3 means? 4 QUESTIONS BY MR. DOVEL: 5 Q. That that's what the woman is 6 going to follow. She's going to take Tylenol 7 and not aspirin, Advil or Aleve. This is our 8 pregnant woman. She's attentive to the 9 doctor's recommendation. 10 MS. BROWN: Objection to the 11 form of the question. 12 QUESTIONS BY MR. DOVEL: 13 Q. Can you see what I've written? 14 A. I do. 15 So you saw -- okay. I see what 16 you're saying. 17 So you're saying if a pregnant 18 woman is following doctor's orders, then she 19 will take Tylenol over those other things? 20 Q. Yes. 21 A. That's the point? 22 Q. Yes. 23 MS. BROWN: And to that 24 question and to this document, I 25 object. Speculation.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. If a woman fully considers the</p> <p>3 potential risks, she's more likely to take</p> <p>4 Tylenol than aspirin, Advil or Aleve?</p> <p>5 MS. BROWN: Objection to the</p> <p>6 form of the question and to the</p> <p>7 creation of the document.</p> <p>8 THE WITNESS: Yeah, I -- you're</p> <p>9 kind of asking me to speculate on some</p> <p>10 hypothetical people and a hypothetical</p> <p>11 doctor, and I -- it's -- I'm feeling a</p> <p>12 bit uncomfortable here in doing that.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. Well, you can say you don't</p> <p>15 know. But let me just ask the question and</p> <p>16 see if I can get an answer.</p> <p>17 Would you agree, sir, that if a</p> <p>18 woman is the sort of person who fully</p> <p>19 considers the potential risks and the doctor</p> <p>20 explains to her that Tylenol is safe and</p> <p>21 aspirin and Advil and Aleve are not, she's</p> <p>22 more likely to take Tylenol --</p> <p>23 A. How do --</p> <p>24 MS. BROWN: Wait. Hold on.</p> <p>25 Hold on.</p> | <p>1 same reasons, I'd have to say I don't</p> <p>2 know. I mean, it's -- I just don't</p> <p>3 know. No one's -- I've never read any</p> <p>4 literature about looking at pregnant</p> <p>5 women and what they -- do they follow</p> <p>6 doctor's orders, do they not follow</p> <p>7 doctor's orders. How do they weigh</p> <p>8 the costs and benefits of -- and I</p> <p>9 don't know, again, whether every</p> <p>10 pregnant woman does exactly the same</p> <p>11 thing.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. It's not --</p> <p>14 MS. BROWN: Hold on. Hold on.</p> <p>15 Please let him answer, Counsel.</p> <p>16 THE WITNESS: I -- well, I'm</p> <p>17 just -- look, I'm not trying to be</p> <p>18 evasive. I know we talked about being</p> <p>19 evasive. It's not being evasive. I'm</p> <p>20 just saying you're presenting me with</p> <p>21 hypotheticals, hypothetical people,</p> <p>22 considering hypothetical situations,</p> <p>23 and I don't know of any information</p> <p>24 that I can use to answer that</p> <p>25 question.</p> |
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| <p>1 If that was the complete</p> <p>2 question, I object to the form of the</p> <p>3 question.</p> <p>4 THE WITNESS: What I'm saying</p> <p>5 is that I'm not -- I don't have enough</p> <p>6 information to answer the question. I</p> <p>7 don't know anything about the woman.</p> <p>8 I don't know anything about the doctor</p> <p>9 or -- so you're asking me to speculate</p> <p>10 about two hypothetical people, and</p> <p>11 it's in an area, of course, that's</p> <p>12 well outside my professional</p> <p>13 expertise.</p> <p>14 That's --</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. Let's talk about what you would</p> <p>17 expect.</p> <p>18 On average, would you expect</p> <p>19 that a woman that fully considers potential</p> <p>20 risks is more likely to take Tylenol than</p> <p>21 other medications for pains and fever?</p> <p>22 MS. BROWN: Same objections to</p> <p>23 this line of questioning and to the</p> <p>24 creation of this document.</p> <p>25 THE WITNESS: Well, for the</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Well, let's use your common</p> <p>3 sense.</p> <p>4 Would you agree, sir, that if a</p> <p>5 woman is going to fully consider the</p> <p>6 potential risks and a doctor explains to her</p> <p>7 Tylenol is safe, aspirin, Advil and Aleve are</p> <p>8 not, that she's more likely, on average, to</p> <p>9 take Tylenol?</p> <p>10 MS. BROWN: Same objections to</p> <p>11 the same question.</p> <p>12 THE WITNESS: Okay. I'm</p> <p>13 getting a little bit confused here</p> <p>14 because I understand I'm here as an</p> <p>15 expert, not to talk about common</p> <p>16 sense, but we can -- you're still</p> <p>17 talking about a hypothetical average</p> <p>18 person here.</p> <p>19 Now, if somebody -- if you have</p> <p>20 somebody who takes risks seriously and</p> <p>21 who follows doctor's orders, there are</p> <p>22 a class of people like that, then it's</p> <p>23 very likely if the doctor says, you</p> <p>24 shouldn't -- you shouldn't take</p> <p>25 aspirin, et cetera, that that person</p> |

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| <p>1 who's -- takes -- who follows what the 2 doctor says will follow the doctor's 3 orders. 4 But there are many people -- 5 and there's lots of studies of 6 noncompliance that show that people 7 can be noncompliant with medications, 8 for example, that they may not do 9 that. So I don't know who we're 10 talking about here. 11 QUESTIONS BY MR. DOVEL: 12 Q. Well, let's talk about somebody 13 who is inattentive to a doctor's 14 recommendation and don't consider the 15 potential risks. 16 As compared to the attentive 17 person, are they more likely to opt for 18 something other than Tylenol? Are they more 19 likely to take aspirin, Advil or Aleve? 20 MS. BROWN: I object to the 21 form of this entire line of 22 questioning and to the continued 23 creation of the document based on the 24 same form objection. 25 THE WITNESS: I think I'm going</p> | <p>1 answer to that question? 2 MS. BROWN: Objection to the 3 form. 4 THE WITNESS: Well, I do have 5 an answer to the question, which is 6 what I just told you. I understand 7 it's not what you want, but it is -- 8 it is an answer to the question. 9 I'm trying to explain to you 10 that -- why I'm answering the question 11 that way. 12 QUESTIONS BY MR. DOVEL: 13 Q. You don't know? 14 MS. BROWN: Objection to the 15 form. He just answered it. 16 THE WITNESS: I'm saying I 17 don't have the information I need to 18 answer the question, so in that sense, 19 I don't know the answer because I 20 don't have enough information. 21 MR. DOVEL: I'm done with the 22 ELMO for now. 23 MS. BROWN: And, Counsel, I'm 24 sorry to interrupt, just a reminder, I 25 need a break at 10:15. I don't want</p> |
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| <p>1 to have to say that I have no answer 2 to these hypothetical questions about 3 hypothetical people. It's just in an 4 area that's well outside my area of 5 expertise. 6 QUESTIONS BY MR. DOVEL: 7 Q. So if we have a woman who is 8 inattentive to doctor's recommendation and 9 does not consider potential risks, then your 10 answer is you don't know whether they're more 11 likely to take Tylenol or not? 12 MS. BROWN: Same objections to 13 these hypothetical questions and to 14 the creation of the hypothetical 15 chart. 16 THE WITNESS: Well, what I'm 17 saying is that this area is outside my 18 area of expertise, and I -- I'm here 19 to give truthful and accurate answers 20 to you, and I don't know how to answer 21 a question that's about two 22 hypothetical people in an area that's 23 outside my expertise. 24 QUESTIONS BY MR. DOVEL: 25 Q. And so as a result, you have no</p> | <p>1 to interrupt you mid-question. 2 QUESTIONS BY MR. DOVEL: 3 Q. Do you have a mechanism that 4 you use to keep up with literature? For 5 example, a regular Google search or alert 6 that alerts you to new studies about ADHD? 7 A. Yes, I have ways that I keep up 8 with literature. 9 Q. How long have you followed the 10 practice of having ways to keep up with the 11 literature? 12 A. Well, it's something, I 13 suppose, I've done throughout my career, 14 yeah. 15 Q. If a new study comes out 16 regarding the epidemiology of what causes -- 17 withdrawn. 18 If a new epidemiological study 19 comes out regarding the cause of ADHD, is it 20 likely that you see it? 21 MS. BROWN: I object to the 22 form of that question. 23 THE WITNESS: Well, because of 24 my specialty focused on genetics, I'm 25 likely to see it if it involves the</p> |

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| <p>1 genetics of ADHD. Otherwise, I may 2 not see it. 3 QUESTIONS BY MR. DOVEL: 4 Q. Is there a plausible biological 5 mechanism by which genes can cause ADHD? 6 MS. BROWN: Objection to the 7 form. 8 THE WITNESS: Yes. 9 QUESTIONS BY MR. DOVEL: 10 Q. And what is that plausible 11 biological mechanism? 12 A. Well, it would start with the 13 patient who eventually develops ADHD carries 14 one or more variants in the genome. A 15 variant just being a piece -- a variation in 16 a piece of DNA that is used to build -- 17 either build proteins in the cell or regulate 18 the function of cells, and that that variant 19 causes a change -- I believe it would be in 20 the brain -- that changes a pathway in the 21 brain that's relevant to the types of 22 symptoms we see in ADHD. 23 Q. Can you identify what pathway 24 in the brain or what change? 25 A. So the -- if we -- just to</p> | <p>1 studies, we call them bioinformatic studies, 2 which are delving deeper into the data and -- 3 that indicated that pathways involved -- 4 well, certain -- for example, dopaminergic 5 cells were -- genes that are involved in 6 dopaminergic cells were implicated in the -- 7 as well. 8 And so that lends credence to 9 the idea of plausibility, that you have a 10 specific, you know, set of genes that are 11 involved in a pathway that we thought in 12 advance was a pathway that is relevant to 13 ADHD. 14 There are also new genes that 15 were discovered as well -- I won't say new 16 genes, but obviously they're new because they 17 hadn't been discovered before but, yes. 18 So it's for these reasons that 19 we think it's, you know -- it's plausible, 20 and I think almost everybody would agree with 21 this, that these genes -- that these genes 22 and others yet to be discovered play a causal 23 role in ADHD. 24 Q. These are -- withdrawn. 25 Is it a plausible biological</p> |
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| <p>1 finish the question of plausibility, though, 2 it's important to know that when we completed 3 the big genomic studies of ADHD -- and to 4 clarify, these are studies that look at 5 people's DNA, and it's very large studies, 6 ten of thousands of people, so very, very 7 well-powered. 8 One of the key findings from 9 that work was that the top genomic loci that 10 were implicated in ADHD, I believe there were 11 27, they implicated about 76 genes because a 12 genomic locus is sometimes bigger than one 13 gene. And those genes were -- we use the 14 phrase "enriched," that did -- they were 15 enriched for genes that are involved in the 16 brain. 17 And so that led us -- I'm 18 saying "us" now because it was a very big 19 group of scientists involved in this project. 20 I mean, worldwide, so possibly maybe a 21 hundred or more on the paper. 22 But it supports the conclusion 23 that -- which was the hypothesis that the 24 locus of ADHD's pathophysiology is the brain. 25 And then there some other</p> | <p>1 mechanism for ADHD that it is caused by 2 disruption or dysregulation of the 3 dopaminergic neurons? 4 MS. BROWN: Objection to the 5 form. 6 THE WITNESS: I would say 7 that's one of the leading hypotheses. 8 QUESTIONS BY MR. DOVEL: 9 Q. Is it a plausible biological 10 mechanism for the cause of ADHD that is 11 caused in part by dysregulation or disruption 12 of noradrenergic neurons? 13 MS. BROWN: Objection to the 14 form. 15 THE WITNESS: So to clarify, 16 when I say here these are good -- and 17 I'll say this is also a good 18 hypothesis. 19 I'm using -- you're saying 20 plausible, and I know that words are 21 used by different people sometimes in 22 different ways. 23 To me it's -- I use it in the 24 sense of probable, and given what we 25 know about the way the mechanism of</p> |

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| <p>1 action of the medications for ADHD and</p> <p>2 what we know about the functions of</p> <p>3 these pathways in the brain, it's</p> <p>4 probable that once the full pathway is</p> <p>5 worked out, that we will find evidence</p> <p>6 for these being dysregulated by at</p> <p>7 least some of the genes involved in</p> <p>8 ADHD.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Is it the case that when you</p> <p>11 applied the concept of plausible biological</p> <p>12 mechanism and you do in your report, that you</p> <p>13 did it by interpreting the word "plausible"</p> <p>14 to mean probable?</p> <p>15 MS. BROWN: Objection to the</p> <p>16 form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Do you understand that the</p> <p>20 concept of plausible biological mechanism as</p> <p>21 is used in Bradford Hill is not probable, but</p> <p>22 it's, in fact, plausible; that is, possible</p> <p>23 but not yet ruled out?</p> <p>24 MS. BROWN: I object to the</p> <p>25 form of the question.</p> | <p>1 what's to me an important guiding concept in</p> <p>2 science because it guides what scientists do</p> <p>3 and how they develop hypotheses.</p> <p>4 We usually go after -- you</p> <p>5 know, we typically go after hypotheses that</p> <p>6 are probable, that we think there's a good</p> <p>7 probability we're right as opposed to one</p> <p>8 that's merely impossible.</p> <p>9 Q. For a drug exposure to cause</p> <p>10 ADHD -- withdrawn.</p> <p>11 For a drug exposure during</p> <p>12 fetal development to cause ADHD, it's going</p> <p>13 to disrupt one of those neurodevelopmental</p> <p>14 processes we talked about earlier,</p> <p>15 proliferation and migration, differentiation</p> <p>16 and so on, right?</p> <p>17 MS. BROWN: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: Well, we don't</p> <p>20 know -- first of all, we don't know</p> <p>21 which of those functions you</p> <p>22 mentioned, the ones on that graph that</p> <p>23 you showed me -- we don't know which</p> <p>24 of those are dysregulated in ADHD.</p> <p>25 There was some early data from</p> |
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| <p>1 THE WITNESS: I -- could you --</p> <p>2 if you have a copy of Bradford Hill,</p> <p>3 I'd like to take a look at that and</p> <p>4 see where he says that. I don't</p> <p>5 recall that from my reading.</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. Did you see any source that</p> <p>8 said, when we talk about a plausible</p> <p>9 biological mechanism, it must be a probable</p> <p>10 biological mechanism?</p> <p>11 A. So let me -- well, the answer</p> <p>12 to that question, which I will give you</p> <p>13 because -- I understand you're asking me this</p> <p>14 yes or no question, but it's a little more</p> <p>15 than yes or no.</p> <p>16 So I can't cite a source that</p> <p>17 says plausible should always mean probable.</p> <p>18 But I -- from my experience of looking at --</p> <p>19 thinking about causality, thinking about</p> <p>20 these issues, if we let plausible mean</p> <p>21 possible, then it opens the door to</p> <p>22 essentially almost anything.</p> <p>23 And that becomes -- then it</p> <p>24 becomes almost mean -- the word becomes</p> <p>25 almost meaningless, that -- probable is</p> | <p>1 Pohlman's suggesting that neurite</p> <p>2 outgrowth might be involved in ADHD.</p> <p>3 And it's -- again, it's a reasonable</p> <p>4 hypothesis that these might be</p> <p>5 involved in ADHD, but it's at the</p> <p>6 level of -- it's still at the level of</p> <p>7 a hypothesis.</p> <p>8 The only -- you know, the only</p> <p>9 solid information we have about what</p> <p>10 causes the symptoms of ADHD come from</p> <p>11 the studies we talked about before,</p> <p>12 the -- we know about the</p> <p>13 neuropsychopharmacology, the mechanism</p> <p>14 of action of the drugs.</p> <p>15 And we have some of the</p> <p>16 neuroimaging studies, but their</p> <p>17 interpretation is always a little bit</p> <p>18 difficult because it's hard to</p> <p>19 separate out the effects of the</p> <p>20 disease from the effects -- I mean,</p> <p>21 the effects of having a disease versus</p> <p>22 the true pathophysiology of this -- of</p> <p>23 the disease.</p> <p>24 MS. BROWN: Counsel --</p> <p>25 MR. DOVEL: Let's go off the</p> |

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| <p>1 record.</p> <p>2 MS. BROWN: Thank you. Thank</p> <p>3 you. I appreciate it.</p> <p>4 VIDEOGRAPHER: The time right</p> <p>5 now is 10:18 a.m., and we're off the</p> <p>6 record.</p> <p>7 (Off the record at 10:18 a.m.)</p> <p>8 VIDEOGRAPHER: The time right</p> <p>9 now is 10:38 a.m. We're back on the</p> <p>10 record.</p> <p>11 QUESTIONS BY MR. DOVEL:</p> <p>12 Q. I want to turn to the topic of</p> <p>13 gene-by-environment interactions.</p> <p>14 I've got a few specific</p> <p>15 questions. This is not your opportunity to</p> <p>16 give me -- give me your whole lecture on it.</p> <p>17 I've just got a few specific questions, if</p> <p>18 you don't mind.</p> <p>19 MS. BROWN: Well, you should</p> <p>20 answer the question truthfully and</p> <p>21 completely.</p> <p>22 MR. DOVEL: Please limit your</p> <p>23 comments.</p> <p>24 MS. BROWN: Right. But you</p> <p>25 can't instruct him on how he should</p> | <p>1 through genetic expression, right?</p> <p>2 MS. BROWN: Objection.</p> <p>3 Objection to the form.</p> <p>4 THE WITNESS: Right. For that</p> <p>5 to happen, the environmental agent</p> <p>6 would need to get into the cell, have</p> <p>7 to get into the nucleus so it could</p> <p>8 interact with the DNA and create what</p> <p>9 broadly we call an epigenetic mark.</p> <p>10 There are a few different types</p> <p>11 of epigenetic marks, and that changes</p> <p>12 the epigenetic mark. Methylation is</p> <p>13 one --</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. And that, sir -- and that type</p> <p>16 of gene-by-environment --</p> <p>17 A. I --</p> <p>18 Q. I'm sorry.</p> <p>19 A. I just wanted to finish.</p> <p>20 Q. Yes.</p> <p>21 A. So the epigenetic mark can</p> <p>22 change the regulation of -- well, I'm sorry,</p> <p>23 not the regulation. It can -- it can either</p> <p>24 increase or decrease the expression of -- the</p> <p>25 expression of the gene, which means the</p> |
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| <p>1 answer --</p> <p>2 MR. DOVEL: You're still</p> <p>3 talking.</p> <p>4 MS. BROWN: -- which is what</p> <p>5 you just did.</p> <p>6 MR. DOVEL: You're still</p> <p>7 violating the Court's order.</p> <p>8 MS. BROWN: No, it's not -- I'm</p> <p>9 not -- violating the Court's order is</p> <p>10 not on objection. I'm not objecting</p> <p>11 to your question.</p> <p>12 I'm saying, please do not</p> <p>13 instruct him how to answer.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Now, one type of</p> <p>16 gene-by-environment interaction would be</p> <p>17 where some environmental factor modified gene</p> <p>18 expression, right?</p> <p>19 MS. BROWN: Objection to the</p> <p>20 form.</p> <p>21 THE WITNESS: Yes.</p> <p>22 Environmental factors can do that.</p> <p>23 QUESTIONS BY MR. DOVEL:</p> <p>24 Q. In that case, the impact of the</p> <p>25 environmental factor would be mediated</p> | <p>1 degree to which it creates the protein or --</p> <p>2 the degree to which it does the job it's</p> <p>3 supposed do in the cell, the change.</p> <p>4 Q. That type of</p> <p>5 gene-by-environment interaction is sometimes</p> <p>6 referred to as the gene acting as a mediator</p> <p>7 for the environmental factor, right?</p> <p>8 MS. BROWN: I object to the</p> <p>9 form of the question.</p> <p>10 THE WITNESS: I have not seen</p> <p>11 that. I don't know. I'd have to give</p> <p>12 that some thought. You're saying gene</p> <p>13 as the mediator -- gene usually -- I</p> <p>14 mean, gene-environment interactions</p> <p>15 usually concede that as two events are</p> <p>16 needed to -- two events are needed</p> <p>17 to cause something like change in gene</p> <p>18 expression.</p> <p>19 So I don't think we would say</p> <p>20 that the gene is the mediator or the</p> <p>21 environment -- the environmental --</p> <p>22 well, it's the -- in that -- in the</p> <p>23 case we're talking about here, the --</p> <p>24 your hypothetical situation, the</p> <p>25 environmentally induced epigenetic</p> |

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| <p>1 mark, I don't think -- I've never 2 heard -- it's not something that's 3 in the literature I've read where the 4 gene is seen as the mediator itself. 5 QUESTIONS BY MR. DOVEL: 6 Q. Well, in the discussion of 7 sibling-control studies, one of the concerns 8 is whether there were mediators or modifiers 9 that are involved, right? 10 MS. BROWN: Objection to the 11 form. 12 THE WITNESS: Yes. 13 MS. BROWN: Hold on. Just let 14 me object. 15 THE WITNESS: Yes, sorry. 16 MS. BROWN: Objection -- 17 THE WITNESS: Sorry. 18 MS. BROWN: It's okay. 19 Objection to the form. Go 20 ahead. 21 THE WITNESS: Okay. Yes. In 22 the sibling-control studies, the -- 23 one of the issues raised in the -- I 24 can't pronounce the name, Sjölander, 25 SJ -- I'll call it the SJ paper, I</p> | <p>1 MR. DOVEL: -- when he's way 2 off of my question. Yes, I can. 3 MS. BROWN: You can't -- you 4 absolutely cannot. And if that's 5 going to happen -- 6 MR. DOVEL: And I just did. 7 MS. BROWN: And if that's going 8 to happen, we're going to need to call 9 the judge. 10 MR. DOVEL: And we can call the 11 judge with all of these questions. 12 MS. BROWN: Sure. Sure. 13 MR. DOVEL: Absolutely. 14 THE WITNESS: I'm sorry -- 15 MS. BROWN: With all of your 16 questions that have nothing to do with 17 his report -- 18 THE WITNESS: Let's -- 19 MS. BROWN: Wait. Hold on. 20 Here's how it's going to work. 21 Counsel is going to ask a question, 22 and you're going to have the 23 opportunity to truthfully and 24 completely answer it, and then counsel 25 can follow up.</p> |
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| <p>1 think we know what that means, is that 2 if there are familial effects -- a 3 familial effect is something that's 4 shared by siblings like, say, poverty 5 in the family, that is involved in 6 mediating the effects of the event of 7 interest, in this case we're talking 8 about acetaminophen exposure, then 9 that effect -- the effect of the -- 10 sorry. The sibling-control study can 11 remove that mediating effect and can, 12 in a sense, reduce the odds ratio that 13 is produced. 14 Now, that said, what we don't 15 know from the Sjölander paper is that 16 its -- the paper itself -- 17 QUESTIONS BY MR. DOVEL: 18 Q. Sir, you're way off on my 19 question. 20 MS. BROWN: No, but you can't 21 interrupt him. You can move to 22 strike -- 23 MR. DOVEL: I can interrupt him 24 when he's -- 25 MS. BROWN: No, you can't.</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. You're going to have to answer 3 my questions, though, and not give me 4 information that's completely unrelated to my 5 question. 6 MS. BROWN: He's not doing 7 that. 8 QUESTIONS BY MR. DOVEL: 9 Q. I didn't ask you about 10 Sjölander. I didn't ask you about any of the 11 details of that. 12 It's simply about, in that 13 context, you've heard of the words "mediator" 14 and "modifier," true or false? 15 A. The Sjölander paper is the 16 paper that -- 17 Q. I didn't ask about the paper. 18 MS. BROWN: Wait. Well, you 19 can't interrupt him, Counsel. 20 THE WITNESS: I'm trying to 21 explain. 22 MS. BROWN: He's giving you an 23 answer. You have to let him finish. 24 Please, go ahead, Doctor. 25 THE WITNESS: I mean, the</p> |

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| <p>1 Sjölander paper is the paper that your 2 expert uses to base his comments on 3 mediation, moderation. It's actually 4 the -- it's the only paper that is 5 supportive of this idea. That's why 6 I'm mentioning it. 7 I'm not -- I'm not pulling it 8 out of, you know, the ether, so to 9 speak, so...</p> <p>10 QUESTIONS BY MR. DOVEL: 11 Q. You're familiar with the 12 concept of mediators, right? 13 A. I am, yes. 14 Q. And with the concept of 15 modifiers? 16 A. Yes. 17 Q. Now, if we're talking about 18 genes as a mediator that, would be a 19 circumstance where the environment -- a 20 gene-by-environment -- withdrawn. 21 One type of gene-by-environment 22 interaction would be where genes served as a 23 mediator for the environmental effect; that 24 is, the environmental effect modified gene 25 expression, right?</p> | <p>1 effects? 2 MS. BROWN: Object to the form 3 of the question. 4 THE WITNESS: I would agree 5 with that, yes. 6 QUESTIONS BY MR. DOVEL: 7 Q. For example, if there was an 8 environmental effect that had -- withdrawn. 9 If there were an environmental 10 effect, a chemical exposure, that caused 11 oxidative stress, that environmental effect 12 would interact with the genes that also 13 regulate parts of environment -- of oxidative 14 stress, right? 15 MS. BROWN: Objection to the 16 form of the question. 17 THE WITNESS: So for it to be a 18 gene-environment interaction, it would 19 be -- if there was a -- for example, 20 if there was a gene that we discovered 21 in our ADHD, you know, genomic studies 22 that was regulating oxidative stress 23 and the acetaminophen exposure 24 interacted with that gene, that would 25 be gene-environment interaction.</p> |
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| <p>1 MS. BROWN: I object to the 2 form of the question. 3 THE WITNESS: Well, so as I 4 said before, mediate -- we typically 5 think -- we don't think of 6 gene-environment interaction, we think 7 of it as interaction effect, not a 8 mediation effect. 9 So I -- I'm not agreeing with 10 that point that you're -- that you're 11 making there. 12 QUESTIONS BY MR. DOVEL: 13 Q. Would you agree that one type 14 of gene-by-environment interaction would be 15 where the environment modifies gene 16 expression? 17 MS. BROWN: I object to the 18 form of the question. 19 THE WITNESS: I would agree 20 with that, yes. 21 QUESTIONS BY MR. DOVEL: 22 Q. Would you agree that another 23 type of gene-by-environment interaction would 24 be where genes have effects on particular 25 systems that then interact with environmental</p> | <p>1 But to answer your question 2 more fully, you're asking about the 3 pathway itself. 4 QUESTIONS BY MR. DOVEL: 5 Q. Now, the -- you're familiar 6 with the concept of genetic susceptibility; 7 that is, certain genetic traits make one more 8 susceptible to a toxicant? 9 MS. BROWN: I object to the 10 form of the question. 11 THE WITNESS: So I'm familiar 12 with the concept of genetic 13 susceptibility in general, that 14 you're -- the genes that we inherit 15 from our parents can make us more 16 susceptible to a variety of events 17 that occur. 18 (Faraone Exhibits 791 and 792 19 marked for identification.) 20 QUESTIONS BY MR. DOVEL: 21 Q. I'm going to mark as 22 Exhibit 792 the Tylenol versus aspirin 23 document. 24 And 791, the truth seeker/paid 25 testifier document.</p> |

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| <p>1 MS. BROWN: And I object to</p> <p>2 both documents for reasons already put</p> <p>3 on the record.</p> <p>4 (Faraone Exhibit 780 marked for</p> <p>5 identification.)</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. I'm going to mark as</p> <p>8 Exhibit 780 the World Federation ADHD Guide.</p> <p>9 MS. BROWN: Thank you.</p> <p>10 MR. DOVEL: 780? Yeah. 791</p> <p>11 and 792, I just -- you don't have</p> <p>12 those, right?</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. All right. Let's take a look</p> <p>15 at page -- first -- withdrawn.</p> <p>16 First of all, you were involved</p> <p>17 in writing this World Federation of ADHD</p> <p>18 Guide, right?</p> <p>19 A. Yes.</p> <p>20 Q. And what is the World</p> <p>21 Federation of ADHD?</p> <p>22 A. The World Federation of ADHD is</p> <p>23 the international association of</p> <p>24 professionals involved in either treating</p> <p>25 people with ADHD or doing research in the</p> | <p>1 heritability due to the SNPs forming ADHD's</p> <p>2 polygenic architecture."</p> <p>3 Right?</p> <p>4 A. That's correct, yes.</p> <p>5 Q. And that's 22 percent?</p> <p>6 A. That's correct.</p> <p>7 Q. And that was the estimate at</p> <p>8 that time, 22 percent?</p> <p>9 A. Correct.</p> <p>10 Q. More recent studies suggest</p> <p>11 it's 15 percent or less?</p> <p>12 A. That's correct, yes. That's</p> <p>13 the --</p> <p>14 Q. Now, let's just talk about what</p> <p>15 that means.</p> <p>16 We can use the -- we can use</p> <p>17 the ELMO.</p> <p>18 If we've got 100 percent is</p> <p>19 our -- this bar I'm creating, and we've got</p> <p>20 75 percent, that's the heritability of ADHD,</p> <p>21 right?</p> <p>22 MS. BROWN: Objection to the</p> <p>23 demonstrative.</p> <p>24 THE WITNESS: Yes, the</p> <p>25 heritability is 75 percent.</p> |
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| <p>1 area. And it essentially -- it -- its main</p> <p>2 function is to hold meetings every two years</p> <p>3 to bring people together from around the</p> <p>4 world to discuss the latest information about</p> <p>5 ADHD.</p> <p>6 Q. Let's turn to page 6, and</p> <p>7 you'll see that there's a paragraph</p> <p>8 highlighted there.</p> <p>9 You write, "You may recall from</p> <p>10 our discussion of twin studies that ADHD's</p> <p>11 heritability is 74 percent."</p> <p>12 A. I see that.</p> <p>13 Q. A minute ago you said</p> <p>14 76 percent. Is that just another approximate</p> <p>15 estimate?</p> <p>16 A. It's around three-quarters,</p> <p>17 75 percent.</p> <p>18 Q. Approximately 75 percent?</p> <p>19 A. Yeah. The latest estimate is</p> <p>20 in the Faraone, Larson paper.</p> <p>21 Q. And what's the latest number?</p> <p>22 A. It's either 75 or 76. I don't</p> <p>23 remember the exact number.</p> <p>24 Q. And you also write here that</p> <p>25 "The data allowed computation of the</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Now, a portion of that is made</p> <p>3 up by common -- by polygenic risk from common</p> <p>4 genes, right?</p> <p>5 A. That's -- well, we say common</p> <p>6 genetic variants, but, yes, that's --</p> <p>7 Q. Common genetic variants.</p> <p>8 A. Yeah.</p> <p>9 Q. And that's about 15 percent; is</p> <p>10 that right?</p> <p>11 A. Right, it's -- the latest 2023</p> <p>12 paper is 15 percent.</p> <p>13 Q. And another portion of that is</p> <p>14 made up by rare variants, right?</p> <p>15 A. Correct.</p> <p>16 Q. And what's the best estimate</p> <p>17 for that?</p> <p>18 A. We don't actually have a good</p> <p>19 estimate of what that is because that rare</p> <p>20 variant literature is still developing. But</p> <p>21 it's -- yeah, we don't have an estimate of</p> <p>22 that. They have to be discovered and because</p> <p>23 they're rare, it's hard to discover them.</p> <p>24 Q. 15 percent common variants,</p> <p>25 some portion is rare variants.</p> |

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| <p>1 That's some portion that's</p> <p>2 undetermined yet, right?</p> <p>3 A. Correct.</p> <p>4 Q. And then the rest of that would</p> <p>5 be gene-by-environment interactions, right?</p> <p>6 MS. BROWN: Object to the form.</p> <p>7 THE WITNESS: No. Another</p> <p>8 component would be what is known as</p> <p>9 epistasis or gene-gene interaction.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. Would you agree, sir, that it's</p> <p>12 likely that a good fraction of this</p> <p>13 heritability is explained by</p> <p>14 gene-by-environment interactions?</p> <p>15 MS. BROWN: Objection to the</p> <p>16 form.</p> <p>17 THE WITNESS: Well, no, because</p> <p>18 the -- we have to go back to the</p> <p>19 definition of heritability. And I</p> <p>20 wish I had one of these ELMOs so that</p> <p>21 I can draw on for you because I could</p> <p>22 show it to you. It's easier to draw</p> <p>23 the equation, but you might want to</p> <p>24 write it out, if you want to, for us.</p> <p>25 So heritability --</p> | <p>1 A. -- it's -- no. It's a</p> <p>2 complicated -- it's really complex. I just</p> <p>3 want to -- because it's hard to -- it's</p> <p>4 actually hard to explain without the</p> <p>5 equation.</p> <p>6 So essentially when</p> <p>7 heritability is computed, and, again, you</p> <p>8 know from the twin study, those components</p> <p>9 can't be computed separately, but the</p> <p>10 heritability can be computed.</p> <p>11 Now, if -- as I said, you</p> <p>12 remember I said the numerator and the</p> <p>13 denominator. Because the gene-environment</p> <p>14 interaction is in the denominator, as</p> <p>15 gene-environment interaction gets bigger,</p> <p>16 heritability gets smaller.</p> <p>17 So when you have -- so high</p> <p>18 heritabilities are -- suggests low</p> <p>19 gene-environment effects. Low heritabilities</p> <p>20 suggests high gene-environment effects. But</p> <p>21 the GxE part is actually in the -- it's not</p> <p>22 in the 75 percent; it's in the 25 percent,</p> <p>23 because it's the numerator and the</p> <p>24 denominator.</p> <p>25 Q. Let's take a look at page 10 of</p> |
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| <p>1 computational heritability is the --</p> <p>2 it's a ratio. It's the ratio of the</p> <p>3 genetic variants, the variants in</p> <p>4 the -- in the disease in this case</p> <p>5 that's due to -- due to genes and</p> <p>6 divided by a rather complicated</p> <p>7 denominator. The bottom -- yeah, yeah</p> <p>8 the lower part of the -- yeah, the</p> <p>9 denominator.</p> <p>10 And that's comprised of the</p> <p>11 genetic variants. We add up four</p> <p>12 components. The genetic variants, the</p> <p>13 environmental variants, if you can</p> <p>14 think of that as the independent</p> <p>15 effects of the environment, and then</p> <p>16 we add gene-environment correlation</p> <p>17 and gene-environment interaction.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Okay. Let's take a look at</p> <p>20 page 10 of the World Federation of ADHD</p> <p>21 Guide.</p> <p>22 A. So I do need to finish</p> <p>23 explaining this because --</p> <p>24 Q. Oh, I'm sorry. I thought you</p> <p>25 finished.</p> | <p>1 the World Federation Guide.</p> <p>2 A. 10. Yes.</p> <p>3 Q. If you look at the bottom</p> <p>4 paragraph, you describe results of studies of</p> <p>5 gene-by-environment interaction, and you say,</p> <p>6 "One of the key findings comes from ADHD GWAS</p> <p>7 studies described in prior section. There we</p> <p>8 reported that only 30 percent of ADHD's</p> <p>9 heritability can be" --</p> <p>10 A. I'm sorry, sir. I'm lost.</p> <p>11 Where -- where --</p> <p>12 MS. BROWN: No worries. I</p> <p>13 think he's pointing you to --</p> <p>14 MR. DOVEL: Page 10.</p> <p>15 MS. BROWN: -- page 10, the</p> <p>16 last paragraph.</p> <p>17 MR. DOVEL: The bottom</p> <p>18 paragraph.</p> <p>19 THE WITNESS: The last para --</p> <p>20 okay. Yeah, I see 30 percent. Yep.</p> <p>21 Yep.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. "Could be you explained" --</p> <p>24 "30 percent of ADHD's heritability could be</p> <p>25 explained by the disorder's polygenic</p> |

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| <p>1 architecture." 2 Right? 3 A. Yeah. To clarify, that's the 4 additive effects of the common variants, not 5 the gene-gene interaction. 6 Q. Right. 7 A. Yeah. 8 Q. That's that -- at that time it 9 was estimated at 22 percent, now it's at 10 15 percent? 11 A. Right. 12 Q. So right now in terms of ADHD's 13 heritability, it's not 30 percent; it's more 14 like a quarter or less of the heritability -- 15 A. Yes. 16 Q. -- is the common, right? 17 A. That's correct, yes. 18 Q. Then look at the next sentence. 19 "Some of the other 70 percent will be 20 accounted for by rare variants, but it is 21 likely that a good fraction of heritability 22 will be explained by gene-by-environment 23 interactions." 24 A. Okay. So that -- 25 Q. Is that true?</p> | <p>1 mathematical equation. It's not 2 something that's, you know, defined by 3 a sentence. It's defined by a 4 mathematical equation. 5 I can see why this one is 6 not -- could be misunderstood. 7 The point is, is that to 8 understand heritability, you need to 9 understand gene-environment 10 interaction. 11 QUESTIONS BY MR. DOVEL: 12 Q. Is it true, sir, that a good 13 fraction of heritability of ADHD is likely to 14 be explained by gene-by-environment 15 interaction? 16 MS. BROWN: Objection to the 17 form. 18 THE WITNESS: So if we go back 19 to your diagram where you had the 20 75 percent and 25 percent. The 21 gene-environment interaction is in the 22 25 percent part of it, not the 23 75 percent of it. It's in the 24 denominator of the equation. 25</p> |
| Page 146 | Page 148 |
| <p>1 A. Well, so that sentence is -- 2 unfortunately is easily misinterpreted. I 3 see now why you -- 4 Q. But is it true? 5 MS. BROWN: Well, he's about to 6 explain that. Let's let him finish, 7 please. 8 THE WITNESS: I'm trying to 9 explain that. Okay. 10 So I can see why -- I 11 understand your question now. 12 What we're trying to say there 13 is if you want to understand 14 heritability, you need to understand 15 the gene-environment interaction. 16 Because the gene-environment 17 interaction goes into the computation 18 of heritability. 19 In retrospect, it would have 20 been better, in fact, better to 21 actually put the equation in the 22 paper, which we didn't do. 23 But the role that 24 gene-environment interaction plays in 25 heritability is -- it's defined by a</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Well, let's take a look at what 3 you say in paragraph -- on page 10 there. 4 You're identifying -- you're 5 explaining in paragraph 10 what portion of 6 the 74 percent, approximately, heritability 7 of ADHD is attributed to. 8 A portion of it is the common 9 genetic variants. That's that 30 percent, 10 right? Yes? 11 A. What I'm telling you is that 12 the sentence itself is inartfully written, 13 and I wish I had written it differently and 14 put the equation in there, and it's -- well, 15 yes. 16 Q. This sentence is talking about, 17 then, the rest of the heritability. That 18 75 percent, right? That's what it's talking 19 about, yes or no? 20 A. What I'm saying is that 21 interpretation of the sentence is not 22 correct. 23 Q. When it says "some of the other 24 70 percent will be accounted for," it's 25 talking about the 70 percent of the</p> |

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| <p>1 heritability, right?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form.</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. As contrasts -- as contrasted</p> <p>6 with the 30 percent which was in the previous</p> <p>7 sentence, right?</p> <p>8 A. Right. So what I'm saying is</p> <p>9 that -- I understand what you're saying, and</p> <p>10 that interpretation of the sentence is not</p> <p>11 correct. So the sentence is not a good</p> <p>12 sentence. I will -- I'm open to say the</p> <p>13 sentence is --</p> <p>14 Q. Is it false?</p> <p>15 MS. BROWN: No, no, sir.</p> <p>16 Please let him finish. Please --</p> <p>17 finish your answer and counsel will</p> <p>18 follow up.</p> <p>19 THE WITNESS: So I'm trying to</p> <p>20 help you understand the intention in</p> <p>21 writing this part and -- is that</p> <p>22 gene-environment interaction and to</p> <p>23 understand heritability, we need to --</p> <p>24 we need to -- we need to understand</p> <p>25 the role of gene-environment</p> | <p>1 millions of words and sentences, and</p> <p>2 there are -- in some cases I don't get</p> <p>3 it exactly right. And this is a case</p> <p>4 where it's -- and this is a case</p> <p>5 that's not actually -- it's easy to</p> <p>6 check. Okay. You can go -- you can</p> <p>7 go back -- in fact, I don't know if</p> <p>8 anybody has a copy of the -- I</p> <p>9 can't -- I'm not allowed to ask for</p> <p>10 papers, right?</p> <p>11 Am I allowed to ask for papers?</p> <p>12 MS. BROWN: No. Just do your</p> <p>13 best to answer the question.</p> <p>14 THE WITNESS: Okay. Okay.</p> <p>15 MS. BROWN: If there's a paper</p> <p>16 that you need to include in your</p> <p>17 answer, you can do that.</p> <p>18 THE WITNESS: Okay.</p> <p>19 You could consult the paper by</p> <p>20 Peter Visscher and Naomi Wray. I</p> <p>21 believe your colleague used it at the</p> <p>22 Chung deposition, and they give --</p> <p>23 they give that equation I talked about</p> <p>24 in their -- in their paper.</p> <p>25</p> |
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| <p>1 interaction, but it -- the sentence</p> <p>2 does a poor job of it because, as you</p> <p>3 read it, it sounds like</p> <p>4 gene-environment -- gene-environment</p> <p>5 interaction itself is heritable when,</p> <p>6 in fact, it's not in the numerator of</p> <p>7 heritability, it's in the denominator</p> <p>8 of heritability.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Well, sir, you said as I read</p> <p>11 it. Did I read the words correctly that you</p> <p>12 wrote?</p> <p>13 A. You did. You did.</p> <p>14 Q. And you wrote those words?</p> <p>15 A. Well, I'm a coauthor, so I</p> <p>16 either wrote them or approved them, but,</p> <p>17 yeah, either -- either/or.</p> <p>18 Q. Those words were in your brain,</p> <p>19 right? You understood what they meant when</p> <p>20 you wrote them, right?</p> <p>21 MS. BROWN: Objection to the</p> <p>22 form.</p> <p>23 THE WITNESS: So I will say</p> <p>24 that in my lifetime of writing papers</p> <p>25 and coauthoring papers, I have written</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Let me ask this then, sir.</p> <p>3 The heritability of 74 percent</p> <p>4 does not mean we can explain 74 percent of</p> <p>5 ADHD etiology by genes. Instead, it means we</p> <p>6 can explain 74 percent of ADHD etiology by</p> <p>7 genes and their interactions with the</p> <p>8 environmental risk factors.</p> <p>9 Is that true?</p> <p>10 MS. BROWN: Objection to the</p> <p>11 form.</p> <p>12 THE WITNESS: No, we can</p> <p>13 explain more -- well, no, no. The</p> <p>14 heritability is just -- the definition</p> <p>15 of heritability is the -- it's a very</p> <p>16 technical definition. It's the</p> <p>17 percentage of variability of ADHD in</p> <p>18 the population under study that is</p> <p>19 explained by genes.</p> <p>20 The rest of it is due to</p> <p>21 environmental effects and -- well,</p> <p>22 included in environmental effects is</p> <p>23 measurement error, which we don't</p> <p>24 really know what that is, but it's --</p> <p>25</p> |

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| <p style="text-align: right;">Page 153</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Are you asserting here that the</p> <p>3 heritability of 74 percent is -- means that</p> <p>4 we can explain 74 percent of ADHD etiology by</p> <p>5 genes?</p> <p>6 A. Well, you know, I'm kind of --</p> <p>7 you know, I'm parsing this in a technical way</p> <p>8 just because it's -- the definition itself is</p> <p>9 technical. So the definition of heritability</p> <p>10 is -- it's what I told you. Okay. It's</p> <p>11 the -- it's the percentage of variability of</p> <p>12 ADHD in the population under study that is</p> <p>13 attributed to genes as opposed to</p> <p>14 environmental effects.</p> <p>15 Q. Sir, when you wrote the World</p> <p>16 Federation of ADHD Guide, did you believe</p> <p>17 that the 74 percent heritability of ADHD</p> <p>18 means that we can explain 74 percent of</p> <p>19 ADHD's causation by genes and their</p> <p>20 interactions with environmental risk factors?</p> <p>21 MS. BROWN: Same objection to</p> <p>22 the same question.</p> <p>23 THE WITNESS: So for clarity, I</p> <p>24 didn't write the guide. I coedited</p> <p>25 the guide with people. I wrote -- I</p> | <p style="text-align: right;">Page 155</p> <p>1 form. The same question.</p> <p>2 THE WITNESS: No. No.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. These symptoms of ADHD, do they</p> <p>5 appear on a spectrum among people?</p> <p>6 A. Yes. Some people have more or</p> <p>7 less -- I mean, to be diagnosed, you have to</p> <p>8 have at least six symptoms.</p> <p>9 But, yes, some people have 18</p> <p>10 symptoms. Some people have -- I'm sorry, you</p> <p>11 have six -- if you're a child. We're talking</p> <p>12 about kids. Kids have to have six symptoms,</p> <p>13 adults can have five.</p> <p>14 Q. If we look at the population as</p> <p>15 a whole, we can have ADHD -- modest ADHD</p> <p>16 symptoms in some people, more ADHD symptoms</p> <p>17 in others, then finally some where they</p> <p>18 have -- have a --</p> <p>19 A. Oh.</p> <p>20 Q. -- have a diagnosis, right?</p> <p>21 A. Yeah. Misunderstood you, your</p> <p>22 question.</p> <p>23 Yes. So if you measure</p> <p>24 symptoms in the population, you get roughly a</p> <p>25 normal distribution of symptoms that, you</p> |
| <p style="text-align: right;">Page 154</p> <p>1 coauthored this chapter and maybe</p> <p>2 another chapter, I don't know, but I</p> <p>3 definitely coauthored this chapter.</p> <p>4 So the answer to your question</p> <p>5 is that back when this was written,</p> <p>6 2017, the definition of heritability</p> <p>7 was the same as it is now. I mean,</p> <p>8 this is -- this is one thing which is</p> <p>9 not up for really discussion because</p> <p>10 it's a mathematical equation.</p> <p>11 And it is what I said before.</p> <p>12 The percentage of variability of ADHD</p> <p>13 in the population that's accounted for</p> <p>14 by genes as opposed to the effects of</p> <p>15 the environment.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. Did you understand my question?</p> <p>18 A. I thought I did, but if you can</p> <p>19 ask it again, if you think I did not respond</p> <p>20 appropriately.</p> <p>21 Q. Do you ever believe that the</p> <p>22 74 percent heritability meant that 74 percent</p> <p>23 of ADHD's etiology is caused by genes and</p> <p>24 gene-by-environment interactions?</p> <p>25 MS. BROWN: Objection to the</p> | <p style="text-align: right;">Page 156</p> <p>1 know, is most -- you know, most people have</p> <p>2 kind of -- kind of an average amount of</p> <p>3 symptoms and then it kind of tails off at</p> <p>4 both ends. A few people have lots of</p> <p>5 symptoms, there's a few people who have</p> <p>6 minimal symptoms.</p> <p>7 But in that sense, it's a</p> <p>8 spectrum in a population.</p> <p>9 Q. Now, in your report, you</p> <p>10 discuss oxidative stress, and you point to</p> <p>11 some evidence showing that at low doses</p> <p>12 acetaminophen can cause or can protect from</p> <p>13 oxidative stress.</p> <p>14 Did you lay out the evidence</p> <p>15 that you were aware of showing that</p> <p>16 acetaminophen at normal therapeutic doses can</p> <p>17 cause oxidative stress?</p> <p>18 A. Can you tell me which paragraph</p> <p>19 you're talking about now in the report?</p> <p>20 Q. Well, I didn't see that in your</p> <p>21 report anywhere, so I don't think it's in</p> <p>22 your report. I just want you to confirm that</p> <p>23 that's not there.</p> <p>24 MS. BROWN: You referenced his</p> <p>25 report.</p> |

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| <p>1 THE WITNESS: I'm just asking 2 what section you're referring to so I 3 can just take a quick look to see. 4 Because you asked me about something 5 in the report, so I can't answer it 6 without looking at the report. 7 QUESTIONS BY MR. DOVEL: 8 Q. Well, do you recall any place 9 where you laid out the evidence that 10 acetaminophen at normal therapeutic doses can 11 cause oxidative stress? 12 A. Again, I'm not really trying to 13 be evasive here. I'm just trying to -- you 14 know, to be able to answer that truthfully 15 and accurately, I need to look at the report. 16 Because you're asking me, is this in the 17 report. 18 So I -- I'm not here, you know, 19 to -- I can't -- I don't remember every 20 sentence that was written in the report. I 21 don't remember every citation that was in the 22 report. So I can't -- I can't answer that. 23 Q. Well, do you recall in the 24 process of preparing your report -- 25 MS. BROWN: Please, Counsel,</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Yeah. 3 A. Well, again, we need to look at 4 the report to see what I did or didn't say 5 about that. I mean, I can tell you my -- if 6 want to know my thoughts about that, I can -- 7 I'm happy to, you know, tell you about that 8 today. 9 Well, let's take a look at the 10 report. 11 Q. Well, I was asking about 12 preparation of the report. If you don't 13 recall, that's fine. 14 Let's take a look at 15 Exhibit 785. That's the Joseph, Faraone 16 article from 2015. 17 A. Oh, yeah. I know what that one 18 is. Yeah, I know. 19 MS. BROWN: Just take a minute. 20 THE WITNESS: Yeah. Yeah. I 21 got it. 22 (Faraone Exhibit 785 marked for 23 identification.) 24 QUESTIONS BY MR. DOVEL: 25 Q. This is an article entitled</p> |
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| <p>1 let him finish. You've interrupted 2 him many times today. 3 THE WITNESS: I'm done. You go 4 ahead. 5 QUESTIONS BY MR. DOVEL: 6 Q. Did you recall during the 7 process of preparing your report that you 8 decided at one point, well, I need to include 9 a section where I lay out all the evidence 10 showing that acetaminophen can cause 11 oxidative stress? Do you recall doing that? 12 MS. BROWN: Objection to the 13 form. 14 THE WITNESS: I don't have any 15 recollection of that right now. 16 QUESTIONS BY MR. DOVEL: 17 Q. Did you have the thought that, 18 well, at least I should lay out the evidence 19 that oxidative stress does play a role in the 20 pathophysiology of ADHD? 21 MS. BROWN: I object to the 22 form of that question. 23 THE WITNESS: Well, I'm sorry. 24 You're asking me if I thought I should 25 do that?</p> | <p>1 "Oxidative stress and ADHD, a meta-analysis." 2 Right? 3 A. That is correct. 4 Q. And you were the lead author on 5 this? 6 A. Well, Joseph is the leader 7 author. I was the last author. 8 Q. And by last author, what does 9 that mean? The senior author? 10 A. It usually means that. Not 11 always. But in this case, it's senior 12 author. 13 Q. Let's start with page 920. On 14 the right column, third paragraph, the 15 article states, "Despite these limitations, 16 our meta-analyses provide preliminary 17 suggestive evidence that oxidative stress 18 plays a role in the pathophysiology of ADHD." 19 Right? 20 A. Yeah, that's correct. I point 21 out that in a -- important part of these 22 results is that the results themselves, they 23 were not statistically significant as it says 24 in the abstract. And so that's why we use 25 the phrase "preliminary suggestive" --</p> |

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| <p>1 "preliminary suggestive." 2 It means that it was -- we 3 thought very useful for hypothesis 4 generation, perhaps following up these 5 results, but it was kind of warning people 6 that our interpretation was that these were 7 very preliminary. 8 Q. The reason that you were 9 involved in writing this paper is before you 10 got involved, there was also evidence that 11 oxidative stress plays a role in the 12 pathophysiology of ADHD, right? 13 A. Other people had indeed 14 discussed that. 15 Q. And they provided evidence 16 showing that oxidative stress plays a role in 17 the pathophysiology of ADHD, right? 18 A. All of the studies up until 19 then, including our own, they're in the kind 20 of realm of, what I would say, hypothesis 21 development. Pointing to a hypothesis that 22 is worth following up, but none of the 23 studies have -- none of the studies up until 24 then, and even until now, have documented 25 oxidative stress as a -- you know, a</p> | <p>1 that when -- it's as you -- I think you know 2 that when you do these kind of studies, you 3 do analyses to try to determine whether your 4 primary analysis, if you will, your initial 5 analysis, might have made a mistake in -- or 6 might be overestimating, or even in some 7 cases, I suppose, even underestimating your 8 findings. 9 In this case, when we adjusted 10 interested for intrastudy clustering, which 11 was appropriate for this particular dataset, 12 you know, one does not always do that, but 13 it's appropriate, I mean, for this dataset 14 because they were -- that just means that 15 there were multiple studies in the same 16 group, then we lost the statistical 17 significance. 18 Q. On page 919, you describe the 19 results of the data that showed an increased 20 ratio of oxidative to antioxidative status in 21 ADHD. 22 So paragraph 2, left column. 23 Do you see that? 24 A. Ah, hold on a second. 25 Yeah, I do. That was where</p> |
| Page 162 | Page 164 |
| <p>1 pathophysiologic pathway in ADHD that we can 2 be certain of. 3 I would say that it -- in terms 4 of levels of certainty, it doesn't even come 5 anywhere near the degree to which we would 6 talk about noradrenergic and dopaminergic 7 systems as being involved in ADHD. Those, 8 for example, are highlighted in the paper 9 that Nature asked me to write for their 10 review journal. 11 Q. Now, a minute ago you said that 12 the results of this paper were statistically 13 insignificant. 14 If we take a look at the 15 abstract, it says, "We found a significant 16 association between ADHD and oxidative stress 17 that could not be accounted for by 18 publication bias." 19 Right? 20 A. And then the next sentence? 21 Q. You write that it "lost 22 significance after correcting for intrastudy 23 clustering, and no one observation accounted 24 for the positive results." 25 A. Right. So what that means is</p> | <p>1 we're giving an interpretation of some of the 2 data. 3 Q. And the interpretation 4 suggested the possibility that ADHD people 5 cannot mount a sufficient response to 6 increased oxidative stress, right? 7 A. Yes. And, again, using the 8 phrase "suggests the possibility," indicating 9 that it is a -- it is a hypothesis. We're 10 not -- we're not taking these data and 11 saying, hey, oxidative stress is an important 12 pathway for ADHD. 13 Q. Now more -- 14 MS. BROWN: Wait. Wait. He's 15 not done. 16 THE WITNESS: Thank you. 17 I think it's -- it's important 18 that whoever is reading all this 19 understands that when one does 20 research projects, we're testing 21 ideas, we're looking at the data and 22 then when we interpret them, we try to 23 come up with the most reasonable 24 interpretation. 25 And here, because we found the</p> |

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| <p>1 results lost their significance after 2 intrastudy clustering, and for other 3 reasons the, you know, the -- you 4 know, the results were not significant 5 for the antioxidant measures, they 6 were for the oxidative stress 7 measures, we are presenting our 8 interpretation as -- in a very -- 9 what's the word for it? -- tenuous 10 way, and that then suggests the 11 possibility. It's -- 12 QUESTIONS BY MR. DOVEL: 13 Q. Were the results significant 14 for the oxidative stress measures? 15 A. Not after correcting for 16 intrastudy clustering. 17 Q. Now, there's more recent data 18 that suggests that mitochondrial dysfunction 19 plays a role in the pathophysiology of ADHD, 20 right? 21 MS. BROWN: Objection to the 22 form. 23 THE WITNESS: Yeah. I am 24 somewhat familiar with that 25 literature.</p> | <p>1 into -- the data ultimately suggested 2 that oxidative stress was not going to 3 be important in ADHD. 4 So I don't -- my -- I 5 personally am not going after that 6 work in my own lab. 7 QUESTIONS BY MR. DOVEL: 8 Q. Is mitochondrial dysfunction a 9 major source of reactive oxygen species? 10 MS. BROWN: Same objection. 11 THE WITNESS: Okay. Well, I'll 12 preface with saying I'm not a 13 mitochondria expert, but my 14 understanding is that, yes, it is a 15 source of oxidative stress and 16 reactive oxygen species. 17 QUESTIONS BY MR. DOVEL: 18 Q. Have scientific studies found 19 elevated levels of oxidative stress in 20 patients diagnosed with ADHD? 21 A. That takes us back to the 22 Joseph paper, and I think we discussed what 23 the paper shows already. 24 The paper examined that 25 hypothesis, it looked at studies that had</p> |
| Page 166 | Page 168 |
| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. And you were familiar with it 3 when you wrote your report, right? 4 A. Somewhat familiar with it, yes. 5 Q. Mitochondrial dysfunction, 6 that's a major source of the reactive oxygen 7 species that leads to oxidative stress, 8 right? 9 MS. BROWN: I object to the 10 form of the question. 11 Go ahead, Doctor. 12 THE WITNESS: Yeah. 13 So this is part of -- this is 14 part of the -- one area of research, 15 which is the idea that mitochondria 16 may be involved in ADHD or other 17 psychiatric disorders. It's a 18 hypothesis that has been developed by 19 a number of people and continues to 20 be -- continues to be looked at. And 21 I hope people will continue to look at 22 it. 23 In my own work I stopped 24 looking at it because after we tested 25 this in two papers, we essentially ran</p> | <p>1 measured what we call -- well, first of all, 2 I should clarify here that we're -- all of 3 these studies are looking at peripheral 4 measures of oxidative stress. They're not 5 looking at the effects of oxidative stress on 6 the brain. 7 Both of these studies are -- 8 cannot -- because of the nature of the work, 9 they can't tell us whether these levels of 10 oxidative stress are causing ADHD or an 11 effect of ADHD. 12 And the result of the 13 meta-analysis when we pried -- when we 14 applied the appropriate corrections showed 15 that the results were not significant. 16 (Faraone Exhibit 784 marked for 17 identification.) 18 QUESTIONS BY MR. DOVEL: 19 Q. I'm going to mark as 20 Exhibit 784 the Khoury, Faraone paper. 21 MS. BROWN: Thank you. 22 QUESTIONS BY MR. DOVEL: 23 Q. Let's take a look at page 347. 24 A. 347? 25 Q. 347.</p> |

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| <p>1 A. Yeah. I'm there.</p> <p>2 Q. There's a highlighted paragraph</p> <p>3 in the middle. The sentence begins, "As the</p> <p>4 major source of reactive oxygen species,</p> <p>5 mitochondrial dysfunction has been linked to</p> <p>6 noradrenergic disorders."</p> <p>7 Right?</p> <p>8 A. This is -- yes. I see that,</p> <p>9 yeah.</p> <p>10 Q. And then it continues on about</p> <p>11 "Evidence suggesting a role for inflammation</p> <p>12 in the pathogenesis of ADHD is consistent</p> <p>13 with a meta-analysis finding elevated levels</p> <p>14 of oxidative stress in patients diagnosed</p> <p>15 with ADHD."</p> <p>16 Right?</p> <p>17 A. I see that, yes.</p> <p>18 Q. This is a paper that you're the</p> <p>19 lead author on -- the lead author on and was</p> <p>20 published in 2022?</p> <p>21 A. I'm the last author on the</p> <p>22 paper, yes.</p> <p>23 Q. You're the senior author?</p> <p>24 A. That's correct.</p> <p>25 Q. And is it true that a</p> | <p>1 association study, the first author was</p> <p>2 Demontis, right?</p> <p>3 A. Yep.</p> <p>4 Q. In that study, you also had</p> <p>5 some supplementary tables that weren't</p> <p>6 published with the original publication that</p> <p>7 are available online, right?</p> <p>8 A. Correct.</p> <p>9 (Faraone Exhibit 744 marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MR. DOVEL:</p> <p>12 Q. Let's mark Supplementary</p> <p>13 Table 9 as Exhibit 744.</p> <p>14 Now, in that study, you</p> <p>15 identified 76 genes that were identified as</p> <p>16 ADHD risk genes, right?</p> <p>17 A. Correct.</p> <p>18 Q. And then you looked at</p> <p>19 associations of those genes, those ADHD</p> <p>20 genes, with genes that were associated with</p> <p>21 various biological pathways, right?</p> <p>22 A. Let me take a quick look here.</p> <p>23 It's been a while since I looked at this.</p> <p>24 Okay. So I -- first, I need to</p> <p>25 explain what the 76 -- what are called</p> |
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| <p>1 meta-analysis found elevated levels of</p> <p>2 oxidative stress in patients diagnosed with</p> <p>3 ADHD?</p> <p>4 A. That's the paper we just</p> <p>5 reviewed, and we found there were elevated</p> <p>6 levels, but that, unfortunately, lost -- the</p> <p>7 elevated levels lost significance after</p> <p>8 correcting for intrastudy clustering.</p> <p>9 Q. Has oxidative stress also been</p> <p>10 implicated in the lower brain volumes seen in</p> <p>11 patients with ADHD?</p> <p>12 A. That is a hypothesis about why</p> <p>13 people with ADHD have -- well, children with</p> <p>14 ADHD, I should say, have -- in some regions</p> <p>15 of the brain have smaller brain volumes on</p> <p>16 average than people without ADHD.</p> <p>17 Q. Is that sentence that appears</p> <p>18 here true, "Oxidative stress has also been</p> <p>19 implicated in the lower brain volume seen in</p> <p>20 patients with ADHD"?</p> <p>21 A. Let me just take a look at what</p> <p>22 we're citing there.</p> <p>23 Oh, yeah, that's -- so this</p> <p>24 was -- that's correct, yes.</p> <p>25 Q. In your most recent genomewide</p> | <p>1 candidate risk genes.</p> <p>2 And this study identifies 27</p> <p>3 genomewide significant loci. Those loci</p> <p>4 incorporate these 76 genes.</p> <p>5 So some, but not all, of these</p> <p>6 genes will eventually be hopefully validated</p> <p>7 as the genes that are -- that are the risk</p> <p>8 genes for ADHD.</p> <p>9 But at this -- at this stage --</p> <p>10 I should say the causal genes for ADHD. At</p> <p>11 this stage, all we know is that they're in</p> <p>12 the causal regions, to clarify that point.</p> <p>13 Q. These are plausible ADHD risk</p> <p>14 genes, right?</p> <p>15 A. They are plausible ADHD risk</p> <p>16 genes, yes.</p> <p>17 Q. And those genes are associated</p> <p>18 with certain biological pathways, right?</p> <p>19 Some of the genes?</p> <p>20 A. Can you give me the paper so I</p> <p>21 can see where we talk about this table in the</p> <p>22 paper itself?</p> <p>23 Q. I'd be happy to, but I just</p> <p>24 want to talk about the table first and see if</p> <p>25 we can understand what we're saying.</p> |

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| <p>1 A. Well, I have to -- I have to 2 see the paper to know exactly what was done 3 in the table. The paper describes what was 4 done in the table. 5 Q. Well, this title says, "Results 6 from analysis of the 76 ADHD candidate risk 7 genes for enrichment in biological pathways." 8 Right? Isn't that what it 9 says? 10 A. Yeah, that's what it says. All 11 I'm asking for is to see what we said about 12 it in the paper to give me context of -- 13 typically in these papers, we may not discuss 14 this table, but we may have discussed this 15 paper. 16 I would like to see what was in 17 the paper at the table. 18 Q. We'll get into that. 19 One of them, biological 20 pathways, was one involved with IL2 21 production. 22 Do you see that? 23 A. I do, yes. 24 Q. Another was IL6 production, 25 right?</p> | <p>1 form of the question. 2 THE WITNESS: Again, I -- what 3 it -- what it -- I really would like 4 to see the paper to understand 5 what's -- what's -- what exactly we've 6 said about this and the methodology 7 here. 8 But, yes, it -- what this is 9 referring to is that -- that this 10 particular -- is it -- genes in this 11 particular database were implicated. 12 QUESTIONS BY MR. DOVEL: 13 Q. Did you quote this in your 14 report, or did you ignore it? 15 MS. BROWN: Objection to the 16 form. Argumentative. 17 THE WITNESS: Well, I have to 18 look at the report to be sure, but if 19 I had to take my best guess, I would 20 say it's not in the report. And -- 21 QUESTIONS BY MR. DOVEL: 22 Q. Is it the case -- 23 MS. BROWN: He's not done. 24 THE WITNESS: Yeah. I -- 25 MS. BROWN: Please.</p> |
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| <p>1 A. I do. 2 Q. That refers to the interleukin 3 cytokines that control inflammation in the 4 body, right? 5 A. I believe that's correct. I'm 6 not an expert in that area. 7 Q. And another biological pathway 8 that was identified with these ADHD risk 9 genes was oxidative stress, right? 10 MS. BROWN: I object to the 11 form. 12 THE WITNESS: You're talking 13 about the CORUM number 2? 14 QUESTIONS BY MR. DOVEL: 15 Q. Yeah, it's the FOX03. 16 A. Yes. 17 Q. You're familiar with FOX03, 18 right? 19 A. It's -- FOX genes are typically 20 regulatory genes. I have to check the FOX03 21 to be sure, but -- 22 Q. It's stated here that the FOX03 23 gene is a gene that regulates oxidative 24 stress, right? 25 MS. BROWN: Objection to the</p> | <p>1 THE WITNESS: What I'm saying 2 is that I would -- I would need to see 3 the paper to understand why it was not 4 in the report. 5 QUESTIONS BY MR. DOVEL: 6 Q. Is it the case, sir, that in 7 their Joseph paper that the data suggested 8 the possibility that ADHD people were more 9 susceptible to oxidative stress? 10 MS. BROWN: Objection to the 11 form. 12 THE WITNESS: That was part of 13 the -- what we called our preliminary 14 suggestive evidence that -- well, I 15 have to -- the way we phrased it had 16 to do with -- let me just take a quick 17 look. 18 QUESTIONS BY MR. DOVEL: 19 Q. Well, the direct quote was -- 20 MS. BROWN: Wait, wait. His 21 answer -- he's trying to answer you. 22 THE WITNESS: I'm just -- 23 MS. BROWN: Just let him 24 finish. 25 THE WITNESS: It was -- it had</p> |

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| <p>1 to do with insufficient ability to</p> <p>2 mount the response, I believe. Let me</p> <p>3 just see --</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. Yeah, page 919, left column,</p> <p>6 paragraph 2.</p> <p>7 A. Yes.</p> <p>8 Q. It suggests the possibility</p> <p>9 that ADHD people cannot mount a sufficient</p> <p>10 response to increased --</p> <p>11 A. Cannot mount a sufficient</p> <p>12 response.</p> <p>13 Q. -- oxidative stress?</p> <p>14 A. Yes.</p> <p>15 Q. And they're more susceptible to</p> <p>16 oxidative stress, right?</p> <p>17 MS. BROWN: I object to the</p> <p>18 form of the question.</p> <p>19 THE WITNESS: We can't say yet</p> <p>20 that they're more suscept --</p> <p>21 susceptible. What we can say that</p> <p>22 with this -- what -- the goal of this</p> <p>23 paper is to present the data to the</p> <p>24 fields and to say, we have found some</p> <p>25 preliminary suggestive evidence, which</p> | <p>1 definitive, but you found evidence of it --</p> <p>2 A. Correct.</p> <p>3 Q. -- right?</p> <p>4 And you didn't mention that in</p> <p>5 your report, did you?</p> <p>6 MS. BROWN: Objection to the</p> <p>7 form of the question.</p> <p>8 THE WITNESS: Well, see, I</p> <p>9 would have to see the report so I</p> <p>10 could explain to you how oxidative</p> <p>11 stress is discussed in the report.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. Now, oxidative stress is also</p> <p>14 observed in people diagnosed with autism,</p> <p>15 right?</p> <p>16 A. I am not here to talk about</p> <p>17 autism.</p> <p>18 Q. You may not want to, but I'm</p> <p>19 going to ask you questions about it.</p> <p>20 MS. BROWN: Well, hold on.</p> <p>21 Hold on. Let's do this the right way.</p> <p>22 He'll ask a question. If you</p> <p>23 don't have an answer, you'll just tell</p> <p>24 him that.</p> <p>25 THE WITNESS: Okay. That's --</p> |
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| <p>1 is what -- one of the things that we</p> <p>2 do in science.</p> <p>3 It's not overinterpreted. I'm</p> <p>4 not saying, hey, I'm sure that ADHD</p> <p>5 people are susceptible to oxidative</p> <p>6 stress.</p> <p>7 You know, for example, so far,</p> <p>8 we don't have any antioxidants that</p> <p>9 are dramatically effective for</p> <p>10 treating ADHD as one example of why we</p> <p>11 were hoping, you know, some people --</p> <p>12 when we were studying oxidative stress</p> <p>13 with the hope of developing better</p> <p>14 treatments.</p> <p>15 But the point here is that it's</p> <p>16 suggesting the possibility that ADHD</p> <p>17 people cannot -- well, suggests the</p> <p>18 possibility is important.</p> <p>19 So I just want to clarify that</p> <p>20 point.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Right.</p> <p>23 You found evidence in 2015 that</p> <p>24 ADHD people cannot mount a sufficient</p> <p>25 response to increased oxidative stress, not</p> | <p>1 fine. I just -- I don't know all the</p> <p>2 rules here, so I'm learning.</p> <p>3 MS. BROWN: No, your answer is</p> <p>4 perfectly fine.</p> <p>5 THE WITNESS: Okay.</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. Oxidative stress has been</p> <p>8 observed both in people diagnosed with ADHD</p> <p>9 and in people diagnosed with autism, right?</p> <p>10 MS. BROWN: Objection to the</p> <p>11 form.</p> <p>12 THE WITNESS: Well, I've</p> <p>13 already answered about ADHD. I have</p> <p>14 no answer regarding autism. I'm not</p> <p>15 familiar with the autism literature.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. Didn't you write an entire</p> <p>18 paper about autism?</p> <p>19 A. I did write a paper about --</p> <p>20 about autism and ADHD.</p> <p>21 (Faraone Exhibit 777 marked for</p> <p>22 identification.)</p> <p>23 QUESTIONS BY MR. DOVEL:</p> <p>24 Q. 777 will be the Antshel,</p> <p>25 Faraone paper.</p> |

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| <p>1 A. Okay. Well...</p> <p>2 MS. BROWN: Just take a moment.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. Let's take a look at 1118,</p> <p>5 right column.</p> <p>6 A. Ah, okay. Interesting.</p> <p>7 Q. There you write that oxidative</p> <p>8 stress has been observed in both ADHD and</p> <p>9 autism, right?</p> <p>10 A. This is a -- I need to see that</p> <p>11 line. Where is that line here? Oh, yeah. I</p> <p>12 see -- yeah, yeah, it has -- yeah, yeah. I</p> <p>13 see what you're saying. Let me just take a</p> <p>14 look at this here. Okay. Okay. I see</p> <p>15 your -- I see what you're reading.</p> <p>16 Q. Would you agree, sir, that</p> <p>17 oxidative stress has been observed in both</p> <p>18 ADHD and autism?</p> <p>19 A. So the best I can recollect</p> <p>20 this paper, because I'm -- it's been a while</p> <p>21 since I've -- I -- I've looked at it, is</p> <p>22 that -- when was this? As of, what, about</p> <p>23 ten years ago, here we're citing two papers;</p> <p>24 one is, I believe, an ADHD paper, and one is</p> <p>25 an autism paper indicating that these papers</p> | <p>1 Q. Science, scientific paper,</p> <p>2 right?</p> <p>3 A. It's -- yeah, it's a</p> <p>4 peer-reviewed paper in a scientific --</p> <p>5 Q. Is this a true statement,</p> <p>6 "oxidative stress has been observed in both</p> <p>7 ADHD and autism"?</p> <p>8 MS. BROWN: Objection to the</p> <p>9 same question.</p> <p>10 THE WITNESS: Well, yes,</p> <p>11 it's true, and then there's two</p> <p>12 citations that are there to support</p> <p>13 that statement, so, yes.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Let's go back to your Joseph</p> <p>16 paper, Exhibit 785.</p> <p>17 On page 919, you describe</p> <p>18 there --</p> <p>19 A. What page? I'm sorry, 919?</p> <p>20 Q. 919.</p> <p>21 A. Yeah.</p> <p>22 Q. What oxidative damage can do.</p> <p>23 You say one of the things it can do is lead</p> <p>24 to altered protein structure.</p> <p>25 That's in the left column,</p> |
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| <p>1 had -- provide evidence -- hold on a second</p> <p>2 here.</p> <p>3 Yeah, that there were some --</p> <p>4 okay. So -- I've forgotten the question,</p> <p>5 so...</p> <p>6 Q. Do you agree, sir, that</p> <p>7 oxidative stress is found in both folks with</p> <p>8 ADHD and in folks with autism?</p> <p>9 MS. BROWN: Objection to the</p> <p>10 form.</p> <p>11 THE WITNESS: So I have not</p> <p>12 tracked the autism oxidative stress</p> <p>13 literature, so I really can't talk</p> <p>14 about that.</p> <p>15 What I can say about ADHD is</p> <p>16 that it has been an intriguing</p> <p>17 hypothesis. In my own work, it</p> <p>18 hasn't -- what's the word for it? It</p> <p>19 hasn't panned out the last -- the last</p> <p>20 paper that we wrote about that.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Antshel was a peer-reviewed</p> <p>23 paper, right?</p> <p>24 A. Let's see. This is Expert</p> <p>25 Review of Neurotherapeutics. Yes.</p> | <p>1 second paragraph.</p> <p>2 Do you see that?</p> <p>3 MS. BROWN: Counsel, I</p> <p>4 apologize, what exhibit are you on?</p> <p>5 MR. DOVEL: 785.</p> <p>6 MS. BROWN: Thank you.</p> <p>7 THE WITNESS: I do see this.</p> <p>8 Yes. Altered protein -- yes. Yes.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. What is altered protein</p> <p>11 structure?</p> <p>12 A. It just means you can change</p> <p>13 the -- it can change the protein. Proteins</p> <p>14 have called a -- they have -- well, they have</p> <p>15 a shape to them, right?</p> <p>16 They're three-dimensional</p> <p>17 objects, very tiny of course in the cell, and</p> <p>18 they have a shape to them. If you change the</p> <p>19 shape, you potentially change the function of</p> <p>20 the protein.</p> <p>21 Q. You also state here that</p> <p>22 oxidative stress can lead to altered</p> <p>23 localization.</p> <p>24 What's that?</p> <p>25 A. So within the cell, for the</p> |

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| <p>1 cell to operate properly, it's important 2 that -- well, cells basically are a bunch of 3 proteins that communicate with each other. 4 So for a protein to communicate 5 correctly in its biological pathway, it needs 6 to be in the right place because the cell 7 itself has its own little separate 8 compartments. 9 And if a protein ends up in the 10 wrong compartment, it's unable to do the job 11 it's supposed to do in that compartment. 12 Q. Can oxidative stress lead to 13 epigenetic modification to DNA? 14 MS. BROWN: Objection to the 15 form. 16 THE WITNESS: Yes. 17 QUESTIONS BY MR. DOVEL: 18 Q. If a fetus experienced 19 sustained oxidative stress during 20 neurodevelopment and that perturbed and 21 disrupted the processes of proliferation and 22 differentiation and so on, could that result 23 in neurodevelopmental disease? 24 MS. BROWN: Objection to the 25 form of the question.</p> | <p>1 MS. BROWN: Objection to the 2 form. 3 THE WITNESS: I'm going to have 4 to look at his report to -- I read so 5 many reports, I'm not -- I don't 6 recall if -- that specific section. 7 If you can pull it out, I can 8 understand what's being said there. 9 (Faraone Exhibit 721 marked for 10 identification.) 11 QUESTIONS BY MR. DOVEL: 12 Q. I'm going to mark as 13 Exhibit 721 a document called "Redox 14 signaling for proliferation and 15 differentiation." 16 I don't think you've ever seen 17 this diagram before. You may have -- 18 A. It's new. It's new to me. 19 Q. -- but I just want to talk to 20 you about the concept here. 21 MS. BROWN: Object to the 22 document. 23 QUESTIONS BY MR. DOVEL: 24 Q. If we look on the X axis, you 25 see it's got ranges from oxidizing to</p> |
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| <p>1 THE WITNESS: It's a hypothesis 2 that is worth following up. 3 QUESTIONS BY MR. DOVEL: 4 Q. Why is it worth following up? 5 A. For the reasons you mentioned 6 here, that there are data that's -- 7 indicate -- well, we know -- we know that 8 oxidative stress has an impact on the brain, 9 and we know that the brain -- well, we 10 believe -- we're pretty sure that the brain 11 is involved in ADHD. 12 And so there are -- well, of 13 course there are many biological pathways 14 that are in the brain, and dysregulation of 15 any of them potentially could lead to ADHD. 16 So I'm a big fan of people 17 studying these hypotheses and taking them as 18 far as they can to help us understand ADHD. 19 I -- I personally hit a dead-end with 20 oxidative stress, but... 21 Q. Now, in Dr. Cabrera's report, 22 he described how oxidative stress regulates 23 the proliferation and differentiation of 24 neurons. 25 Do you recall that?</p> | <p>1 reducing. That's different levels of 2 oxidative stress in a cell. 3 Do you see that? 4 A. I do see that, yes. 5 Q. And on the Y axis, we've got 6 level of activity for various things, 7 including differentiation and proliferation. 8 Do you see that? 9 A. I do, yes. 10 Q. Do you see this indicates that 11 with more reduced conditions, that is lower 12 levels of oxidative stress, proliferation 13 increases? 14 A. I do see that, yes. 15 Q. And there's kind of a sweet 16 spot in the middle where differentiation is 17 at its height. 18 Do you see that? 19 A. I -- 20 MS. BROWN: Objection to the 21 form of the question. 22 Go ahead. 23 THE WITNESS: In the middle 24 there, yes. Differentiation is right 25 there in the green -- the green</p> |

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| <p style="text-align: right;">Page 189</p> <p>1 section.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Now, do you dispute</p> <p>4 Dr. Cabrera's assertion that levels of</p> <p>5 oxidative stress in the fetus can impact the</p> <p>6 differentiation and proliferation of neurons?</p> <p>7 MS. BROWN: I object to the</p> <p>8 form of the question.</p> <p>9 THE WITNESS: I -- I'm not</p> <p>10 disputing that oxidative stress can</p> <p>11 have those effects. It's not my</p> <p>12 expertise, but I'm also not disputing</p> <p>13 it.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. If it impacts proliferation --</p> <p>16 withdrawn.</p> <p>17 If increased oxidative stress</p> <p>18 in the fetus impacts proliferation,</p> <p>19 differentiation of neurons, can that result</p> <p>20 in neurodevelopmental disorders?</p> <p>21 MS. BROWN: Objection to the</p> <p>22 form of the question.</p> <p>23 THE WITNESS: Well, we just --</p> <p>24 we don't know. We just don't know.</p> <p>25</p> | <p style="text-align: right;">Page 191</p> <p>1 risk factors can increase the likelihood of</p> <p>2 oxidative stress?</p> <p>3 MS. BROWN: Objection to the</p> <p>4 form.</p> <p>5 THE WITNESS: I would agree</p> <p>6 that that's possible.</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. Dr. Cabrera asserts and cites</p> <p>9 studies that NAPQI exerts oxidative stress</p> <p>10 and depletes glutathione in the brain even at</p> <p>11 relatively low doses.</p> <p>12 Do you dispute that?</p> <p>13 MS. BROWN: Objection to the</p> <p>14 form.</p> <p>15 THE WITNESS: I didn't come</p> <p>16 here to dispute Dr. Cabrera. It's not</p> <p>17 my area of expertise. I came here as</p> <p>18 an expert in the area of ADHD.</p> <p>19 So I didn't come here to</p> <p>20 comment on Dr. Cabrera's report. I</p> <p>21 don't -- I don't really have any</p> <p>22 comments on it because not being an</p> <p>23 expert in that area, I'm not the</p> <p>24 person to -- I can't give you any</p> <p>25 truthful, accurate response about</p> |
| <p style="text-align: right;">Page 190</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. You don't think it's</p> <p>3 possible --</p> <p>4 MS. BROWN: Counsel, when you</p> <p>5 get to a good spot, could we take a</p> <p>6 break?</p> <p>7 MR. DOVEL: Sure.</p> <p>8 MS. BROWN: Thank you.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. You don't think that's</p> <p>11 possible?</p> <p>12 MS. BROWN: Objection to the</p> <p>13 form.</p> <p>14 THE WITNESS: It's possible in</p> <p>15 the sense that it's a hypothesis that</p> <p>16 one could study, and we would have</p> <p>17 to -- one would have to do a series of</p> <p>18 studies to document that oxidative</p> <p>19 stress is occurring in the brains of</p> <p>20 people with ADHD and that it's causing</p> <p>21 their ADHD.</p> <p>22 I haven't -- I haven't seen</p> <p>23 those studies that document that.</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. Do you agree that environmental</p> | <p style="text-align: right;">Page 192</p> <p>1 something where I'm not an expert in.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Well, do you dispute that fact,</p> <p>4 that NAPQI exerts oxidative stress and</p> <p>5 depletes glutathione in the brain even at</p> <p>6 relatively low doses?</p> <p>7 MS. BROWN: Same objections to</p> <p>8 the form of that question.</p> <p>9 THE WITNESS: Well, my answer</p> <p>10 is the same as the answer I gave you</p> <p>11 to the previous -- the previous</p> <p>12 question.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. Which is you don't dispute it?</p> <p>15 MS. BROWN: No. That was not</p> <p>16 the answer. I object.</p> <p>17 THE WITNESS: The answer was</p> <p>18 that this is -- you're asking me a</p> <p>19 question that's way outside my area of</p> <p>20 expertise. And I'm not here to con --</p> <p>21 confirm or dispute anything</p> <p>22 Dr. Cabrera -- Dr. Cabrera wrote in</p> <p>23 his report about the neurobiology of</p> <p>24 oxidative stress.</p> <p>25 MR. DOVEL: All right. Let's</p> |

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| <p>1 go off the record.</p> <p>2 VIDEOGRAPHER: The time right</p> <p>3 now is 11:38 a.m., And we are off the</p> <p>4 record.</p> <p>5 (Off the record at 11:38 a.m.)</p> <p>6 VIDEOGRAPHER: The time right</p> <p>7 now is 11:59 a.m. We are back on the</p> <p>8 record.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Is it useful to expose pregnant</p> <p>11 mice and rats to a chemical to see if that</p> <p>12 would cause neurodevelopmental changes in the</p> <p>13 brains of the mice or the rats?</p> <p>14 A. No.</p> <p>15 Q. It's not useful at all?</p> <p>16 A. I did think that was useful at</p> <p>17 one point in time, but I have since changed</p> <p>18 my opinion on that.</p> <p>19 Q. Is the scientific consensus</p> <p>20 that it's useful to expose pregnant mice and</p> <p>21 rats to a chemical to see if it causes</p> <p>22 neurodevelopmental changes in the offspring?</p> <p>23 A. That's hard to say that there's</p> <p>24 a consensus. I do know that people still do</p> <p>25 these kinds of studies. I know from talking</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. I didn't actually ask you if</p> <p>3 you mentioned it in your report.</p> <p>4 A. Oh.</p> <p>5 Q. In the course of doing your</p> <p>6 work in this case, did you run across studies</p> <p>7 that had those results?</p> <p>8 Let's take it in pieces.</p> <p>9 A. Okay.</p> <p>10 Q. In doing your work in this</p> <p>11 case, did you look at studies that -- where</p> <p>12 acetaminophen was given to pregnant mice or</p> <p>13 rats?</p> <p>14 A. Yes.</p> <p>15 Q. Did you see in these studies</p> <p>16 where -- when pregnant mice or rats were</p> <p>17 exposed to acetaminophen, the offspring had</p> <p>18 dysregulation in the dopamine system?</p> <p>19 A. Well, that's where I'd need to</p> <p>20 check the report because if I -- if I -- if I</p> <p>21 looked at and mentioned, it would be in the</p> <p>22 report.</p> <p>23 Q. Okay. We'll get to that then.</p> <p>24 A. Okay.</p> <p>25 Q. Has any scientific study</p> |
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| <p>1 to colleagues, even the director of the</p> <p>2 National Institutes of Mental Health once,</p> <p>3 about the kinds of studies they were</p> <p>4 encouraging. They're moving away from</p> <p>5 studying mice and rats and looking for more</p> <p>6 human-relevant studies such as do marmosets</p> <p>7 have bigger frontal lobes or organoids and</p> <p>8 other kind of cell lines to try to solve the</p> <p>9 problem. The problem, of course, is not</p> <p>10 having access to the human brain for many of</p> <p>11 these studies.</p> <p>12 Q. Has any -- withdrawn.</p> <p>13 In doing your work in this</p> <p>14 case, did you observe scientific studies</p> <p>15 demonstrating that prenatal exposure to rats</p> <p>16 and mice to acetaminophen would perturb the</p> <p>17 dopamine system in the offspring?</p> <p>18 MS. BROWN: Objection to the</p> <p>19 form.</p> <p>20 THE WITNESS: Well, as I said</p> <p>21 in the report -- well, I guess, first,</p> <p>22 I'm sorry. You asked me if I've</p> <p>23 mentioned that in my report, and I'm</p> <p>24 going to ask you again if I can look</p> <p>25 at my report.</p> | <p>1 identified a meaningful difference between</p> <p>2 humans on one hand and rodents on the other</p> <p>3 such that if we give a prenatal exposure to</p> <p>4 acetaminophen to a rodent and it perturbs the</p> <p>5 dopamine system, it's not going to happen in</p> <p>6 a human?</p> <p>7 MS. BROWN: Objection to the</p> <p>8 form.</p> <p>9 THE WITNESS: So there are</p> <p>10 studies that document that the brains</p> <p>11 of rodents and humans are dramatically</p> <p>12 different. Just that's -- it's --</p> <p>13 again, I can -- the details are all in</p> <p>14 the report, so I'm not going to repeat</p> <p>15 them here, but we can look at that.</p> <p>16 They differ in size, cell types.</p> <p>17 Most -- the most important -- I</p> <p>18 guess most relevant to that -- I mean,</p> <p>19 the entire brain is relevant, of</p> <p>20 course, but the frontal lobes of the</p> <p>21 brain, the human brain, are believed</p> <p>22 to be important in self-regulation,</p> <p>23 including the self-regulation of</p> <p>24 activity, attention, and impulsivity.</p> <p>25 And basically the rat and the</p> |

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| <p>1 mouse have, you know, almost no 2 frontal lobe. And so the dopaminergic 3 neurons that communicate from areas in 4 the striatum that eventually send 5 signals to the frontal lobes, you 6 can't really study that effectively 7 in the rat or the mouse. 8 QUESTIONS BY MR. DOVEL: 9 Q. Exhibit 716 identifies some 10 steps for neurodevelopment. 11 Do all of these steps take 12 place in the mice and rats as well? 13 MS. BROWN: Objection to the 14 form. Objection to the exhibit. 15 THE WITNESS: I -- yeah, right. 16 Wait. Sorry. Gosh. 17 MS. BROWN: It's okay. Just -- 18 just -- it's okay. You're doing 19 great. 20 THE WITNESS: That's known as 21 impulsivity, by the way, but, yeah. 22 So I'm just not an expert in 23 rat and mouse brain development, so I 24 don't have an answer to that. 25</p> | <p>1 MS. BROWN: Objection to the 2 form. 3 THE WITNESS: Oh, yeah. 4 Objection to the form. 5 So, you know, I don't know if 6 anybody has ever compared human and 7 rodent catecholaminergic neurons. And 8 by "catecholaminergic," I mean 9 dopaminergic or noradrenergic. 10 QUESTIONS BY MR. DOVEL: 11 Q. Has there any -- withdrawn. 12 Can you cite to any study that 13 has identified a difference between humans 14 and mice and rats that would tell us that if 15 we give acetaminophen to a pregnant rat or 16 mice and it causes neurodevelopmental 17 disorders, that's not going to happen in a 18 human? 19 MS. BROWN: Objection to the 20 form of the question. 21 THE WITNESS: I'm just reading 22 your question again to make sure I get 23 it right. 24 So there's no study that has 25 created a neurodevelopmental disorder</p> |
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| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Is there anything about the 3 dopamine system and the noradrenaline system 4 in mice and rats that differs between -- 5 differs with humans? 6 Let me rephrase the question. 7 Is there any difference between 8 the dopamine and noradrenaline systems in 9 humans that differs from rats and mice? 10 A. Well, because their brains are 11 so different -- the brains are dramatically 12 different that the -- well, of course -- 13 maybe I should -- okay. When you say "does 14 the system differ," what's -- what do you 15 mean by the system differing? 16 Q. Well, they both have dopamine 17 neurons, right? 18 A. Correct. 19 Q. They both have noradrenaline 20 neurons, right? 21 A. Yes. 22 Q. Is there anything about the 23 dopaminergic or the noradrenaline neurons of 24 mice and rats that differs from humans? 25 A. You know, I don't --</p> | <p>1 in a rat or a mouse. So the answer 2 is -- has to be no there. 3 QUESTIONS BY MR. DOVEL: 4 Q. You're familiar with the use of 5 knockout mice to study ADHD? 6 A. I am, yes. 7 Q. There's one knockout mice or 8 mouse where they alter the genes related to 9 dopamine, and they get behaviors that are 10 similar to ADHD in humans, right? 11 A. There are -- I guess, for 12 example, the dopamine transporter in knockout 13 mouse is one of the -- such mouse. 14 Q. And when they take the dopamine 15 transporter in the knockout mouse and they 16 give it the medications that they give 17 people, it helps resolve the ADHD symptoms in 18 the mouse, right? 19 MS. BROWN: Objection to the 20 form of the question. 21 THE WITNESS: So what it 22 does -- well, I'd have to -- do you 23 have a copy of the paper we could look 24 at so I could -- I think it's 25 Gainetdinov was the first author. I</p> |

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| <p>1 would have to see -- do you have the 2 paper? Can I look at the paper? 3 QUESTIONS BY MR. DOVEL: 4 Q. I don't have that. 5 A. You don't have the paper. 6 Okay. That's right. I mentioned it, so, 7 right. That's fine. Fair enough. 8 I don't remember how they said 9 they measured ADHD symptoms, but they 10 typically -- what these studies do is 11 measure -- and I'm not saying they did this, 12 but typically what they do is they measure 13 activity level. Something like a mouse 14 running across an open field, and they kind 15 of count the number of times it crosses 16 certain lines, and they have an index of 17 hyperactivity. 18 That's just not -- and as I 19 detail in the report, it's not a good measure 20 of ADHD. It's just a measure of the mouse's 21 activity level. 22 And, in fact, some people use 23 activity level to index anxiety or mania. In 24 fact, someone, I think it was Wickens, did a 25 study and found when you tried to do the same</p> | <p>1 very far since it was first published. And 2 although it was a pretty prestigious journal, 3 I think it was in Science it was published, 4 and the model is essentially -- it 5 basically -- knock out basically means that 6 you -- in this case you eliminate the 7 dopamine transporter to the mouse's brain. 8 The mouse no longer has a dopamine 9 transporter. 10 And that's not the current 11 thinking about ADHD. We -- the current 12 thinking about ADHD is that there are too 13 many dopamine transporters in the brain, not 14 that they're missing dopamine transporters. 15 And that's because 16 methylphenidate, which is a drug they used on 17 the mouse, its main mechanisms of action, 18 what it does, is it blocks the dopamine 19 transporter. So it essentially functionally 20 reduces the number of dopamine transporters. 21 So it was a funny model that 22 way; that it -- it's supposed to be a model 23 of ADHD, but it was -- it was not really, you 24 know, consistent with these other facts that 25 we knew about ADHD.</p> |
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| <p>1 kind of measurement in ADHD kids, this kind 2 of activity in the open field, it didn't 3 actually do a good job differentiating kids 4 with ADHD from kids without ADHD. 5 So the measures themselves are 6 not -- they're not ADHD symptoms. It's 7 typically something that's many steps away 8 from ADHD symptoms. And importantly, and if 9 we look at the -- well, importantly, if we 10 look at the acetaminophen studies that I 11 looked at, none of these studies use what I 12 would consider to be the best validated 13 measures of -- that might be -- might be 14 related to ADHD, and even those have 15 weaknesses. None of them used those. 16 But getting back to the 17 dopamine transporter in knockout mouse, so 18 they did show that you knock out the 19 transporter, this creates this hyperactive 20 mouse that has higher activity levels, and it 21 was normalized with treatment with 22 methylphenidate. 23 The problem with that model -- 24 well, there's two of them. One is -- it 25 hasn't -- as far as I know, it hasn't gotten</p> | <p>1 Q. When you refer to this model of 2 ADHD, you're talking about an animal model? 3 A. I was talking about the 4 knock -- the dopamine transporter knockout 5 mouse, yeah. 6 Q. And the dopamine transporter 7 knockout mouse is sometimes abbreviated to 8 D-A-T or DAT knockout? 9 A. Yes, DAT-KO sometimes, too. 10 Yeah. 11 Q. And the DAT knockout mouse, it 12 engages in hyperactive behavior? 13 MS. BROWN: Objection to the 14 form. 15 THE WITNESS: Yeah. I don't 16 recall exactly what they measured. I 17 believe it was activity level in the 18 open field, but I just -- it's been a 19 long time since I've looked at that 20 paper. 21 QUESTIONS BY MR. DOVEL: 22 Q. Hyperactive, right? 23 A. Well, activity level, which is 24 different. Hyperactivity is a symptom of 25 ADHD. Activity level is the degree to which</p> |

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| <p>1 the mouse runs around in a certain 2 environment that's created for the mouse. 3 Q. You knock out the certain gene, 4 it results in a mouse that engages in much 5 greater activity level as compared to other 6 mice, right? 7 A. Compared to mice that have not 8 had the transporter knocked out. 9 Q. When you give that mouse ADHD 10 medication, the hyperactivity goes away, 11 right? 12 MS. BROWN: Objection to the 13 form. 14 THE WITNESS: My recollection 15 is when you give it methylphenidate, 16 the ADHD -- the -- well, no, not the 17 ADHD. Remember, we're not talking 18 about -- you can't create -- there's 19 no -- there is no way to create the 20 diagnosis of ADHD in a mouse. 21 QUESTIONS BY MR. DOVEL: 22 Q. Let me withdraw and rephrase 23 that question. 24 MS. BROWN: Wait, wait. Wait. 25 Hang on. He's got a finish.</p> | <p>1 had found that giving acetaminophen to 2 pregnant mice or rats would produce changes 3 in the dopamine, noradrenaline and serotonin 4 systems in the mice? 5 MS. BROWN: I object to the 6 document 718, and I object to the form 7 of the question. 8 THE WITNESS: I was aware there 9 were studies like this, yes. 10 QUESTIONS BY MR. DOVEL: 11 Q. Do you agree that if mice or 12 rats are given acetaminophen or exposed to 13 acetaminophen while they're still in the -- 14 before they're born, while they're still 15 fetuses, that that's going to alter the 16 levels of GABA, glutamic acid, noradrenaline, 17 dopamine in the resulting offspring? 18 MS. BROWN: I object to the 19 form of the question. 20 THE WITNESS: So -- well, let's 21 back up a second here. 22 I have to, again, state that 23 I'm not here as an expert in the 24 neurobiology of acetaminophen effects 25 in a mouse or the rat. I'm here as an</p> |
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| <p>1 MR. DOVEL: I'm going to 2 withdraw the question. 3 QUESTIONS BY MR. DOVEL: 4 Q. Is it the case that if you give 5 this knockout mouse ADHD medication, it 6 resolves the hyperactivity symptoms? 7 MS. BROWN: Objection to the 8 form. 9 THE WITNESS: That's my 10 recollection, is that if you give 11 methylphenidate, which is an ADHD 12 medication, it changed the activity 13 level to be similar to the mouse that 14 had the normal dopamine transporter. 15 (Faraone Exhibit 718 marked for 16 identification.) 17 QUESTIONS BY MR. DOVEL: 18 Q. I'm going to mark as Exhibit 19 718, acetaminophen exposure in mice and rats. 20 I've included on Exhibit 718 21 some quotes from studies that were mentioned 22 by Dr. Cabrera and quoted and cited in his 23 report. 24 At the time you wrote your 25 report, you were aware that numerous studies</p> | <p>1 expert in ADHD, and I could certainly 2 talk to you about my experience. 3 The main focus of my report was 4 on the ability to measure symptoms of 5 ADHD in the rat and the mouse model, 6 and also to explain why I thought that 7 the rodent brain was insufficiently 8 similar to the human brain to be 9 useful for drawing plausible 10 biological conclusions for the 11 purposes of a Bradford Hill analysis. 12 QUESTIONS BY MR. DOVEL: 13 Q. Okay. I still need an answer 14 to my question. 15 Do you want me to give it to 16 you again? 17 A. Give it to me again. 18 Q. Sure. 19 A. Yeah. Sorry. I just needed to 20 give you some context there. 21 Q. I'll rephrase it. 22 When you wrote your report, 23 were you aware -- withdrawn. 24 Do you agree that in the 25 studies where rats and mice are exposed to</p> |

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| <p>1 acetaminophen in utero that it results in 2 offspring that have altered levels of GABA, 3 glutamic acid, noradrenaline and dopamine? 4 MS. BROWN: Same objection. 5 Same question. 6 THE WITNESS: That's my 7 understanding, that these studies have 8 found those types of things. 9 But not having, you know, these 10 studies to look at right now, I can't 11 kind of evaluate those sentences that 12 are on the screen. That's what the -- 13 that's what the sentences say that are 14 in front of me. 15 QUESTIONS BY MR. DOVEL: 16 Q. Those are the same 17 neurotransmitters that are implemented -- or 18 implicated in causing ADHD, right? 19 MS. BROWN: Object to the form 20 of the question. 21 THE WITNESS: The strongest 22 ones are the noradrenergic and 23 dopaminergic systems. There's less 24 strong evidence for the other -- more 25 scattered, less certain evidence for</p> | <p>1 object to the form of that question. 2 THE WITNESS: Okay. So in 3 my -- as I've mentioned before, I'm 4 not a physician, so I don't counsel 5 pregnant women about using -- well, I 6 don't counsel pregnant women, period, 7 so it's -- the question really isn't 8 relevant to me. 9 QUESTIONS BY MR. DOVEL: 10 Q. Have you ever given advice to 11 pregnant women about acetaminophen and ADHD? 12 MS. BROWN: Objection to the 13 form of the question. 14 THE WITNESS: It does appear in 15 at least one, maybe two -- well, one 16 blog that I wrote a while back, yes. 17 QUESTIONS BY MR. DOVEL: 18 Q. Okay. Knowing that -- having 19 done the study, seen these mice and rats 20 studies, are you comfortable saying, it's 21 perfectly fine, take as much Tylenol as you 22 want when you're pregnant; it won't have any 23 impact on your child? 24 MS. BROWN: Objection to the 25 form.</p> |
| Page 210 | Page 212 |
| <p>1 the others. 2 QUESTIONS BY MR. DOVEL: 3 Q. Those are the ones that are 4 implicated in the etiology, the cause, of 5 ADHD, right? 6 MS. BROWN: I object to the 7 form of the question. 8 THE WITNESS: Well, I would say 9 the leading candidates are 10 noradrenergic and dopaminergic. 11 Scientists will have discussions about 12 the degree to which serotonin and 13 glutamate and GABA are involved. But 14 there are some -- I would say a low -- 15 a much lower level of certainty. 16 QUESTIONS BY MR. DOVEL: 17 Q. Knowing that we have these many 18 studies with mice and rats, controlled 19 studies that show these changes in the brains 20 of mice and rats and resulting changes in 21 neurotransmitter systems, are you comfortable 22 telling women that it's perfectly fine for 23 them to take acetaminophen when they're 24 pregnant? 25 MS. BROWN: Multiple bases I</p> | <p>1 THE WITNESS: Well, okay. I 2 would -- first of all, if I was 3 approached on the topic, I would say, 4 ask your doctor about it. I'm not 5 going to say, take as much Tylenol as 6 you want. I'm not going to 7 say anything like -- I'm going to say, 8 ask your doctor about it. 9 My understanding from reading 10 some of the, you know, consensus 11 statements and reports from the 12 different associations that 13 currently -- they don't say take as 14 much Tylenol as you want. They say 15 something else. They say it's okay to 16 take Tylenol but limited dosage or 17 something like that. I don't know the 18 exact format. 19 But I'm not -- as I said, I'm 20 not talking to -- counseling women, 21 pregnant women, about their use of 22 Tylenol. 23 (Faraone Exhibit 719 marked for 24 identification.) 25</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. 719, Principles of statistical</p> <p>3 tests and p-values.</p> <p>4 Do you sometimes give tests to</p> <p>5 your students?</p> <p>6 MS. BROWN: I object to 719,</p> <p>7 and I object to any questions</p> <p>8 regarding this true-or-false document.</p> <p>9 MR. DOVEL: Limit it to form,</p> <p>10 please.</p> <p>11 MS. BROWN: I object to the</p> <p>12 form of 719.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. Do you sometimes give tests to</p> <p>15 your students?</p> <p>16 A. Well, I for -- well, the last</p> <p>17 15 years of -- I don't give tests in the</p> <p>18 sense of, you know, true/false tests to</p> <p>19 students.</p> <p>20 I work primarily -- I shouldn't</p> <p>21 say primarily. Well, okay.</p> <p>22 My -- I work essentially with</p> <p>23 graduate students that want to work with me</p> <p>24 and do research. I don't give them tests of</p> <p>25 this sort. I mean, they do have to pass like</p> | <p>1 What -- is the -- but are you asking</p> <p>2 me true or false? Is this true or</p> <p>3 false?</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. Yes.</p> <p>6 A. Okay.</p> <p>7 MS. BROWN: And I will object</p> <p>8 to the form of the question that is</p> <p>9 asking for a true or false.</p> <p>10 THE WITNESS: Okay. And I will</p> <p>11 say it -- it depends on how that</p> <p>12 p-value -- the p-value that's been</p> <p>13 recorded in the paper and what</p> <p>14 actually was done in that paper.</p> <p>15 It -- did they correct for multiple</p> <p>16 testing? Did they not correct for</p> <p>17 multiple testing?</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Let's suppose --</p> <p>20 MS. BROWN: Wait. Were you</p> <p>21 finished?</p> <p>22 THE WITNESS: I'm done for now,</p> <p>23 so we can --</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. Let's suppose we've got an</p> |
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| <p>1 a doctoral dissertation exam where they, you</p> <p>2 know -- they're asked about things.</p> <p>3 That's a test of sorts, but</p> <p>4 it's not a written test here.</p> <p>5 Q. Do you understand what a</p> <p>6 true/false test is?</p> <p>7 A. I do, yes. Yes.</p> <p>8 Q. Let's take a look at these,</p> <p>9 number 1. "A p-value greater than .05 means</p> <p>10 that no effect was observed."</p> <p>11 True or false?</p> <p>12 MS. BROWN: I object to the</p> <p>13 form of the question.</p> <p>14 THE WITNESS: Am I taking this</p> <p>15 test now? I'm sorry. I don't</p> <p>16 understand.</p> <p>17 MS. BROWN: No, you're not here</p> <p>18 to take a test.</p> <p>19 THE WITNESS: I'm sorry.</p> <p>20 MR. DOVEL: You're answering my</p> <p>21 questions.</p> <p>22 MS. BROWN: You're just here to</p> <p>23 answer questions, if you can. If you</p> <p>24 can.</p> <p>25 THE WITNESS: I'm sorry.</p> | <p>1 accurate analysis that's been appropriately</p> <p>2 corrected, and .05 would be the right value</p> <p>3 for statistical significance, if there was</p> <p>4 statistical significance.</p> <p>5 Is it true or false that a</p> <p>6 p-value greater than .05 means that no effect</p> <p>7 was observed?</p> <p>8 MS. BROWN: I object to the</p> <p>9 form of the true/false question.</p> <p>10 THE WITNESS: All right. So</p> <p>11 if -- let me restate it, and we can</p> <p>12 agree on the -- restating it this way.</p> <p>13 If someone does a study where</p> <p>14 there's one primary outcome, like an</p> <p>15 FDA registration trial where we say,</p> <p>16 okay, I'm going to -- I'm going to see</p> <p>17 if my drug changes the ADHD rating</p> <p>18 scale, and that's my -- that's the bet</p> <p>19 I'm making on this study, then the</p> <p>20 p-value of .05 is appropriate.</p> <p>21 If the p-value is less than</p> <p>22 .05, it means that we can reject the</p> <p>23 null hypothesis, meaning that -- the</p> <p>24 null hypothesis being that the drug</p> <p>25 does not help people with ADHD.</p> |

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| <p>1 If the p-value is greater than 2 .05, we cannot reject the null 3 hypothesis. That's the technical 4 definition of that p-value. 5 QUESTIONS BY MR. DOVEL: 6 Q. Does that mean that no effect 7 was observed? 8 MS. BROWN: Objection to the 9 form of the question. It's the same 10 question. 11 THE WITNESS: Well, it's not -- 12 well, when you say "no effect," what 13 do you mean by "effect" here? 14 QUESTIONS BY MR. DOVEL: 15 Q. If you're measuring for an 16 effect, cause and effect. 17 A. Well, okay. So we go back to 18 the -- I'm just going to use the drug trial 19 example because that's typically where -- one 20 of the few places where 05 is meaningful 21 because there's one primary outcome, if there 22 is. 23 It means that -- okay. So I 24 think by effect, you mean what's the point 25 estimate of -- in this case the difference</p> | <p>1 effect is 1. 2 It doesn't mean that the effect 3 size was 1. It just means that it was 4 too close to 1 to be able to say that 5 it was statistically significant. 6 QUESTIONS BY MR. DOVEL: 7 Q. Would you say that the study 8 found no association? 9 MS. BROWN: I object to the 10 form of that question. It's the same 11 question. 12 MR. DOVEL: Ally, you're going 13 to have to keep your objections to 14 "objection, form." You can stop 15 coaching this witness. 16 MS. BROWN: That's an improper 17 suggestion. The form of that question 18 is improper, as was the form of the 19 previous question. 20 THE WITNESS: Repeat the 21 question, please. Or I can read it 22 back here. 23 QUESTIONS BY MR. DOVEL: 24 Q. Yeah. 25 If the result of a study has P</p> |
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| <p>1 between two groups. 2 Okay. So it doesn't mean that 3 that difference -- the observed difference 4 was zero. It could be different than zero. 5 It could be less than zero. It could be more 6 than zero. 7 It just means that the size is 8 too small relative to the variability for us 9 to be able to conclude that the drug works. 10 Q. Let's look at question 3. "If 11 the result of a study has P greater than .05, 12 that means the study found no association and 13 no evidence of an effect." 14 True or false? 15 MS. BROWN: I object to the 16 form of the true/false question. 17 THE WITNESS: What it means, if 18 the P is greater than .05, it means 19 that -- that it's -- if they found -- 20 well, let's talk about the effect. 21 You're not telling me what the 22 effect was, so it's the same as the 23 clinical trial we talked about. You 24 could have a -- in this case the 25 association, typically, the null</p> | <p>1 greater than .05, does that mean that the 2 study found no association? 3 MS. BROWN: Object to the form 4 of that question. 5 THE WITNESS: Well, it means it 6 found no association in the sense that 7 if it's properly reported, the 8 investigators will say, we did not 9 find a statistically significant 10 association, so they can't conclude 11 that there is an -- they cannot 12 conclude an association exists. 13 They may report that there's an 14 odds ratio of 1.1, let's say, but they 15 also have to conclude that that 16 association is -- is not different 17 from zero in terms of the statistical 18 tests. 19 QUESTIONS BY MR. DOVEL: 20 Q. Which means we don't know one 21 way or the other? You can't say, hey, 22 there's no association, right? 23 MS. BROWN: I object to the 24 form of the question. 25 THE WITNESS: Well, the</p> |

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| <p>1 proper -- well, I would say that the 2 proper -- the proper conclusion is -- 3 let me think the way you phrased that. 4 Let me look at it again. 5 This means we know -- you know, 6 but we do, right, because we have to 7 compare it to the other outcome? If 8 it -- if it's -- if the p-value is 9 less than .05, then we conclude that 10 there is statistically significant 11 association and that the study 12 supports the idea that for whatever is 13 being studied, that there is -- there 14 is an association. 15 So when it's less than .05, we 16 can conclude the opposite. There's 17 two different conclusions, right? You 18 can't -- you don't get the same 19 conclusion from P greater than less 20 .05. 21 And it's -- if you don't -- if 22 you don't achieve your alpha level, 23 you have to say, I cannot conclude 24 that there's an association. 25 If it's -- you do achieve your</p> | <p>1 form of the question and the document. 2 THE WITNESS: Yeah. I'm sorry, 3 I think I'm on the wrong page. 4 MS. BROWN: Yeah. I think 5 counsel is talking about -- 6 MR. DOVEL: Page 14. 7 MS. BROWN: -- page 14. 8 THE WITNESS: I don't have a 9 page 14. Oh, I'm sorry. It's 10 double-sided. 11 MS. BROWN: No, it's okay. 12 Take your time. 13 THE WITNESS: All right. Wrong 14 page. 15 QUESTIONS BY MR. DOVEL: 16 Q. Let me ask the question again. 17 You see in the middle of the page there's 18 some highlighted text? 19 A. Yes. 20 Q. There it says, "It is a mistake 21 to conclude from P point -- P greater than 22 0.05 that a study found 'no association' or 23 'no evidence' of an effect." 24 Do you agree with that? 25 MS. BROWN: Objection to the</p> |
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| <p>1 alpha level, you concluded that you 2 found an association. 3 (Faraone Exhibit 730 marked for 4 identification.) 5 QUESTIONS BY MR. DOVEL: 6 Q. I'm going to mark as 7 Exhibit 730 an excerpt from Dr. Baccarelli's 8 rebuttal report. 9 MS. BROWN: I'll object to the 10 incomplete nature of Exhibit 730. 11 THE WITNESS: Okay. Let's see. 12 QUESTIONS BY MR. DOVEL: 13 Q. If you look at the second page 14 of this document, you'll see, it's page 14 of 15 Dr. Baccarelli's rebuttal, he quotes some 16 epidemiological experts discussing p-value. 17 One of the quotes he has there 18 is the misconception that a null 19 hypothesis -- null hypothesis p-value greater 20 than .05 means that no effect was observed or 21 that absence of an effect was shown or 22 demonstrated. He says that's a mistake. 23 Do you agree with 24 Dr. Baccarelli's recitation here? 25 MS. BROWN: I object to the</p> | <p>1 form of the question. 2 THE WITNESS: I see what he's 3 saying here. 4 QUESTIONS BY MR. DOVEL: 5 Q. Okay. 6 A. So, you know, I'm actually 7 agreeing with what he says, so that the -- 8 just to kind of map out what I'm saying to 9 what he's saying here. 10 What I've said before is that 11 when the P is greater than .05 for one 12 statistical test, you cannot -- we cannot 13 reject null hypothesis, so we can't reject 14 the idea that in this case -- I'm sorry, wait 15 a second. 16 I got -- yeah. The null 17 hypothesis is no association. So when P is 18 greater than .05, we can't the -- we cannot 19 reject the idea that there's no association. 20 But he's correct in saying that 21 if you want to show that no effect was 22 observed, there's a different kind of test to 23 do that, which it's called an equivalence 24 test, which is infrequently used because it's 25 of low power.</p> |

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| <p>1 So we're both -- we're both 2 right, essentially, about that point. 3 Q. Is there anything in this 4 paragraph that you disagree with? 5 MS. BROWN: Objection to the 6 form of the question. 7 MR. DOVEL: Withdrawn. I'm 8 going to do this differently. 9 THE WITNESS: I'm sorry, my -- 10 MS. BROWN: He withdrew the 11 question. 12 THE WITNESS: Ah, right. Okay. 13 Thank you. 14 MS. BROWN: We'll wait for the 15 next one. 16 QUESTIONS BY MR. DOVEL: 17 Q. Okay. For a scientist to 18 conclude that the data in an epidemiological 19 study supports the claimed results, what are 20 some of the things that they need to look at? 21 MS. BROWN: Objection to the 22 form of the question. 23 THE WITNESS: Could you make it 24 more specific? 25</p> | <p>1 that a study was reliable and could be 2 quoted? 3 A. Well, you certainly want to 4 assess what confounding and biases, 5 differential misclassification bias. 6 Selection -- selection biases would be 7 another one. They are laid out in the report 8 there. 9 You would want to be sure that 10 the study itself was -- well, they're not 11 really design studies, because these studies 12 typically use preexisting databases, but that 13 the approach to using this preexisting 14 database was within, you know, reasonable 15 scientific practice. 16 And that typically involves how 17 they selected people for the study from the 18 larger database, what type of analyses they 19 ran on the -- on the larger database. Those 20 are all the things, of course, that are in 21 the method section of these papers. 22 Q. Before a scientist can conclude 23 that the results of an epidemiological study 24 are empirically supported by strong evidence, 25 do they need to determine that the study</p> |
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| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Sure. 3 A. Are we talking about one of the 4 studies that I've reviewed or some other kind 5 of study? There's lot -- I mean, there are 6 different kinds of epidemiologic studies. 7 Q. Yeah. Let's assume we're 8 talking about an epidemiologic study showing 9 a relationship between some environmental 10 factor and ADHD. Is -- withdrawn. 11 If a scientist is going to 12 conclude that an epidemiological study 13 addressing an environmental factor and 14 ADHD -- scientists can conclude that data -- 15 data supports the conclusion, whatever the 16 conclusion of the study is, does the 17 scientist need to be satisfied that the 18 studies adequately address potential 19 confounders? 20 MS. BROWN: Objection to the 21 form of the question. 22 THE WITNESS: Yes. 23 QUESTIONS BY MR. DOVEL: 24 Q. What other studies would 25 scientists want to examine to be satisfied</p> | <p>1 adequately accounted for potential 2 confounders? 3 MS. BROWN: Objection to the 4 form. 5 THE WITNESS: Well, so here 6 there's a little bit of vagueness in 7 the question, right. So you're 8 saying -- so if you mean by the 9 results, if you're talking about the 10 report of association, is that what 11 you mean? 12 QUESTIONS BY MR. DOVEL: 13 Q. Yes. 14 A. Okay. So if somebody -- if I 15 read an epidemiological study and they say, 16 okay, report of association is 1.2, it's 17 statistically significant, and I'm satisfied 18 with other aspects of the study, then I will 19 look at that and say, okay, this looks like 20 we got a report of a significant association 21 that may be confounded. 22 So that the fact that it's 23 confounded -- the fact that it's confounded 24 doesn't invalid -- invalidate the statistical 25 test. It just means that the odds ratio or</p> |

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| <p style="text-align: right;">Page 229</p> <p>1 the risk ratio that they computed might 2 indicate confounding as opposed to causality. 3 Q. Well, but if -- I'm going to 4 the next step. Let's suppose you're trying 5 to find studies that you think -- where the 6 results are strongly supportive; that is, 7 they take into account of confounders and 8 biases. 9 In that circumstance, you're 10 going to have to examine the study, make 11 certain that they -- the studies adequately 12 addressed all confounders and potential 13 residual confounders as well as biases, 14 right? 15 MS. BROWN: Objection to the 16 form of the question. 17 THE WITNESS: Well, yes. And 18 that I would -- in all of these 19 observational epidemiologic studies, 20 we want to evaluate those issues. 21 QUESTIONS BY MR. DOVEL: 22 Q. If a study is subject to 23 unmeasured confounders or biases, would you 24 conclude that the study is strong evidence of 25 an association?</p> | <p style="text-align: right;">Page 231</p> <p>1 don't even know about, and that's of 2 course impossible to adjust for, and 3 that's one of the reasons why 4 observational epidemiology is 5 considered to be -- these studies are 6 considered to be -- well, which is why 7 they always draw cautious conclusions. 8 And the smaller the risk ratio, 9 the more cautious one gets because as 10 the risk ratio gets small, the 11 likelihood that a confound explains 12 the results increases. 13 So, for example, in the 14 meta-analyses -- I think it was 15 Mesar -- Masarwa, I can't pronounce 16 the name, and I think also -- I think 17 Ricci both did an analysis where they 18 basically show that given the pooled 19 effect size, the pooled risk ratio, 20 which is roughly, let's say, 1.2, 1.3, 21 in those studies, that it would only 22 take a confound that had a risk ratio 23 effect on both the -- the exposure and 24 the outcome, the confounded with a 25 risk ratio of about 2 to totally erase</p> |
| <p style="text-align: right;">Page 230</p> <p>1 MS. BROWN: Objection to the 2 form. 3 THE WITNESS: Well, first, I 4 mean, to conclude it's strong evidence 5 depends on the study itself, right? 6 The -- I don't know -- this is 7 a hypothetical study, so I don't know 8 any of the details. So, you know, I 9 can't say strong, weak or otherwise. 10 The issue of unmeasured 11 confounding is a well-known problem 12 in observational epidemiology. It 13 affects basically every study. 14 It's -- for every study, 15 there's potentially -- well, 16 there's unmeasured confounds that are 17 known confounds, and that's a real 18 problem, such as -- so, for example, 19 in some of the studies that I 20 reviewed, confounding by indication, 21 confounding by genetics or maternal 22 ADHD, were confounds that were not 23 used. 24 Then there's unmeasured 25 confounding that -- of confounds we</p> | <p style="text-align: right;">Page 232</p> <p>1 the association. 2 And so, for example, the -- you 3 know, the maternal ADHD, the risk 4 ratio for that and ADHD is about 30 in 5 probably the best study that's 6 available. And so that is a reason 7 why I view the -- I -- that's the 8 reason why I view and my report says 9 that the non -- not correcting for 10 confounding is a very serious problem 11 with trying to draw conclusions about 12 causality from these studies. 13 QUESTIONS BY MR. DOVEL: 14 Q. If an epidemiological study 15 fails to correct for known confounders, can 16 it still be strong evidence of an 17 association? 18 A. If it fails to correct for 19 known confounders. If it's -- if the risk 20 ratio was -- is large enough, then you would 21 begin to think -- I mean, Bradford Hill 22 basically tells us that, you know, when the 23 risk ratio is -- gets larger, we're less 24 worried about the correction for confounds. 25 And he and everybody recognizes</p> |

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| <p>1 that sometimes you can't correct for known 2 confounds, and so we're stuck -- you know, 3 we're kind of stuck with observational 4 epidemiology with -- we have studies that 5 aren't, you know, sometimes the best study. 6 And then you look at some of the details. 7 And so, I mean, here he talks 8 about -- when he talks about large effects, 9 he's talking about things that range from 10 like 10 to 200. 11 Q. Well, let's make the question 12 about lower risk ratio. 13 A. Yeah. 14 Q. Assume we've got an 15 epidemiological study with a risk ratio of 2 16 or less. If it does not appropriately 17 correct for known confounders, can that still 18 be strong evidence of an association? 19 A. No, that's pretty clear. 20 Bradford Hill more or less says that or 21 implies that in his paper. 22 Q. In your view, there's an 23 epidemiological study that reports a risk 24 ratio of less than 2. If it's strong 25 evidence, that means it's going to correct</p> | <p>1 something which is known as standardized mean 2 difference, but that's translatable 3 mathematically into odds ratios. And it's 4 roughly -- it's roughly, you know, the -- we 5 call a large effect or a strong effect is 6 something that's in the range of 3 or 4. 7 So that's how I -- so if we -- 8 as a group, we came down on this as a -- and 9 which I agree with. I think that's a 10 reasonable -- a reasonable metric. And it's 11 consistent with other -- and I've quoted some 12 other experts in the field about what's -- 13 you know, kind of what's their threshold for 14 small or large and, obviously, every 15 threshold, people have slightly different -- 16 slightly different views, but the experts 17 that I've seen, they kind of all agree that 18 around 3 or 4 is reasonable for large. 19 And even -- you know, Bradford 20 Hill doesn't give an exact threshold. All we 21 know for sure is that he says that 2 is -- 2 22 is too low to be taken too seriously without 23 dealing with confounds. 24 Q. What is a negative control? 25 A. So the concept of a negative</p> |
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| <p>1 for known confounders? 2 MS. BROWN: Objection to the 3 form. 4 THE WITNESS: Well, again, we 5 also -- you know, we have to back up a 6 second and say, what do you mean by 7 "strong" here. 8 QUESTIONS BY MR. DOVEL: 9 Q. In your view strong. 10 A. Well, the problem with the 11 words like "strong" is that it means 12 different things in different settings. 13 So sometimes it's used 14 colloquially. It just means impressive. 15 It's an impressive piece of work. 16 Sometimes strong means, hmm, 17 you know, this is a large -- this is a large 18 odds ratio and that's -- it's used actually 19 to quantify the magnitude of the odds ratio. 20 So, for example, in the -- what 21 we call the International Consensus Statement 22 on ADHD that I cited in the report, we give 23 guidelines for weak, moderate and strong 24 effects. We give them on the -- what's it 25 called? The -- we give them in the metric of</p> | <p>1 control comes from experimental science where 2 you have -- you can actually create real 3 control groups. Negative control is 4 typically lacking some feature that we -- you 5 see in your active group. You have an active 6 group. You have a control group and then -- 7 I'm sorry. You have a negative control, 8 which you're -- well, it can -- it can -- in 9 experimental science, it can mean many -- a 10 number of different things. 11 So in some of the genomic 12 studies, we might use, we're you're trying to 13 do a study of -- say, you know, looking at 14 gene expression in, say -- I'm making this 15 up, right -- for ADHD versus some other 16 group, you might have a negative control. 17 Some group where you expected not to see gene 18 expression, based upon your -- what you -- 19 how you exposed -- whatever samples you were 20 studying, whatever cells typically -- you're 21 exposing cells or you're studying cells that 22 have some genetic variant. 23 It's also -- it's been ported 24 into observational epidemiology and with the 25 acetaminophen studies we see negative</p> |

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| <p>1 controls as maternal use of acetaminophen 2 before and after pregnancy, paternal use of 3 acetaminophen -- yeah, paternal use of 4 acetaminophen. 5 And as I said in the report, 6 I'm not a big fan of negative controls. Now, 7 look, I'm not an epidemiologist. I know the 8 epidemiologists think they're great, but I'm 9 not a big fan of negative controls in 10 epidemiology, in observational epidemiology, 11 the kind of studies we're talking about here. 12 Because what we have is you have -- we'll 13 call it the main study, which is already 14 subjected to confounding, and then you end up 15 creating another study, which itself is 16 subjected to confounding. And so you're 17 dealing with, like, two layers of confounding 18 and -- 19 Q. I just asked you what they 20 were, sir. 21 MS. BROWN: Yeah, but we've got 22 to let him answer, please. 23 THE WITNESS: Well, but I do 24 understand that and I -- 25 MR. DOVEL: We're moving on to</p> | <p>1 control for confounding? 2 MS. BROWN: Objection to the 3 form of the question. 4 THE WITNESS: In general, 5 that's -- I would agree with that 6 statement. 7 QUESTIONS BY MR. DOVEL: 8 Q. Here, you didn't think that 9 there was a valid negative control, right? 10 MS. BROWN: Objection to the 11 form. 12 THE WITNESS: So it's -- 13 that's -- it's not exactly what I said 14 in the report. May I pull the report 15 out to -- so we can actually look at 16 what I said? 17 QUESTIONS BY MR. DOVEL: 18 Q. Yeah, I'm going to pull up the 19 words here and discuss it with you. 20 A. But can I actually look at the 21 report so I can see the context? 22 Q. Yeah, I'm going to -- I'm going 23 to get that for you. 24 MS. BROWN: Sure, you have it 25 in front of you.</p> |
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| <p>1 a different topic. 2 MS. BROWN: I know, but he has 3 to finish his answer. 4 THE WITNESS: I'm trying to -- 5 I'm trying to explain how I view -- 6 I'm using negative controls in my 7 report, so -- 8 QUESTIONS BY MR. DOVEL: 9 Q. I didn't ask that. 10 A. Yeah, well -- 11 MS. BROWN: Okay. But whatever 12 you asked, this is how he's answering 13 it, so let's let him do that. 14 MR. DOVEL: No, he said 15 literally he's answering a different 16 question now. 17 So let me give you a different 18 question. 19 THE WITNESS: Fair enough. I 20 did switch to -- that's fair enough. 21 I did switch to a different question. 22 QUESTIONS BY MR. DOVEL: 23 Q. Do you agree, sir, that 24 epidemiologists in general conclude that if 25 you've got a valid negative control, that can</p> | <p>1 THE WITNESS: Am I allowed to 2 just look at this whenever I want to? 3 MS. BROWN: Yeah, go ahead. 4 Sure. That's why you have it. 5 THE WITNESS: Okay. 6 All right. I've got to find 7 it. I've got to find it. 8 QUESTIONS BY MR. DOVEL: 9 Q. On page 74, page 137. 10 A. 137. I am there. Okay. 11 Q. 73. 12 A. Okay. It -- so, yeah, this 13 basically says in different words what I just 14 said before. 15 Q. All right. Let's talk about, 16 in paragraph 137, at the -- so go over to 17 page 74, you'll see the very last part of 18 137. 19 (Faraone Exhibit 701 marked for 20 identification.) 21 QUESTIONS BY MR. DOVEL: 22 Q. For the record, I'm going to 23 mark -- this is your amended report I'm 24 looking at, and we'll mark this as 25 Exhibit 701.</p> |

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| <p style="text-align: right;">Page 241</p> <p>1 A. I'm sorry, you said -- I think 2 you didn't mean 74. 77, maybe? 3 Q. Page 74 -- 4 MS. BROWN: It looks like -- 5 I'm sorry. You have the expert report 6 and counsel has the amended expert 7 report, so the paragraphs may not 8 be -- 9 MR. DOVEL: We'll give you a 10 copy of your amended report. 11 QUESTIONS BY MR. DOVEL: 12 Q. Page 74, you say, "As a result, 13 maternal ADHD and its attendant genetic risk 14 may be more common in women who use 15 acetaminophen during pregnancy as opposed to 16 those who only use acetaminophen outside of 17 pregnancy." 18 Do you cite any evidence that 19 maternal ADHD is more common in women who use 20 acetaminophen during pregnancy as opposed to 21 women who only use acetaminophen outside of 22 pregnancy? 23 A. Yeah, that is just my expert 24 opinion based upon my knowledge of ADHD. I'm 25 not citing here anything here as a -- it's</p> | <p style="text-align: right;">Page 243</p> <p>1 MS. BROWN: Same objections. 2 QUESTIONS BY MR. DOVEL: 3 Q. If we have somebody who is 4 attentive to the doctor's recommendation, 5 they're more likely to take Tylenol or 6 something else if they've got fever or 7 headache, right? 8 MS. BROWN: Well, I object to 9 that. He didn't agree to that. 10 THE WITNESS: Yeah, I think my 11 recollection is that I decided that -- 12 well, what I said, I should say, about 13 this was I'm being asked hypothetical 14 questions about two hypothetical 15 people, and I'm not comfortable 16 answering those kinds of questions. 17 It just needs -- I need to speculate 18 about things to do that. 19 QUESTIONS BY MR. DOVEL: 20 Q. Well, sir, in your report, you 21 stated your opinion on this, and it's just 22 false, right? 23 You said in your report that 24 women who -- with ADHD who take actions that 25 are -- without considering risk and are</p> |
| <p style="text-align: right;">Page 242</p> <p>1 not meant to be a citation of an empirical 2 study. I'm just -- I'm giving this as an 3 example of a -- of a confound that could 4 occur. 5 We do know from other work that 6 there are differences documented between 7 women who use acetaminophen before and after 8 pregnancy. I think the Stergiakouli paper 9 documents that. But this is one -- I'm just 10 giving the example of an ADHD relevant -- a 11 potential ADHD relevant. 12 Q. Well, what you point to is that 13 patients with ADHD are more likely to take 14 actions without fully considering potential 15 risks and to be inattentive to physician 16 recommendations, right? 17 A. Yes. 18 Q. And that's true, right? 19 A. In general, people -- patients 20 with ADHD are impulsive and inattentive, and 21 it leads to -- it can lead to this kind of 22 behavior, yes. 23 Q. Let's go look at 792 on the 24 ELMO again. 25 A. Oh, gosh.</p> | <p style="text-align: right;">Page 244</p> <p>1 attentive, you said they're going to take 2 acetaminophen? 3 MS. BROWN: Objection to the 4 form of the question. 5 QUESTIONS BY MR. DOVEL: 6 Q. Isn't it the case that women 7 who are inattentive to physician 8 recommendations are more likely to take 9 something other than acetaminophen? 10 MS. BROWN: Objection to the 11 form of the question. 12 THE WITNESS: So you're saying 13 women with ADHD would be more likely 14 to take acetaminophen? 15 QUESTIONS BY MR. DOVEL: 16 Q. Sir, a woman with ADHD, a 17 person who is inattentive to the physician's 18 recommendations, who acts without fully 19 considering risks, they're more likely to 20 take aspirin, Advil or Aleve than a woman who 21 is attentive to a doctor's recommendation, 22 right? 23 MS. BROWN: Same objection to 24 the form of these questions. 25 THE WITNESS: Well, I'm giving</p> |

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| <p>1 an example of what I think, and 2 it's only an example, and it's -- I'm 3 not -- I'm not saying that this -- 4 again, this is not a citation of 5 something -- 6 QUESTIONS BY MR. DOVEL: 7 Q. It's just speculation? 8 MS. BROWN: Wait. Wait. He's 9 got to finish. 10 THE WITNESS: I wouldn't call 11 it speculation. I would say it's 12 based upon my knowledge of ADHD, 13 particularly ADHD in adults, which is 14 also an area of my research. 15 QUESTIONS BY MR. DOVEL: 16 Q. And applying your common sense? 17 MS. BROWN: Please, sir. Let 18 him finish. 19 THE WITNESS: It's not really 20 common -- I wouldn't call it common 21 sense. I would call it the knowledge 22 of the nature of ADHD and how it 23 affects people, and it led me to that 24 conclusion. There's no citation. 25 Clearly, I'm not saying that this was</p> | <p>1 likely to take actions without fully 2 considering potential risks and to be 3 inattentive to physician's recommendations." 4 You wrote those words, didn't 5 you? 6 MS. BROWN: Well, I object to 7 the incomplete reading of the 8 sentence. 9 THE WITNESS: Let's hold on a 10 second. Let me give this some thought 11 here. 12 QUESTIONS BY MR. DOVEL: 13 Q. The question pending is, did 14 you write these words, yes or no? 15 MS. BROWN: That wasn't the 16 question pending. 17 THE WITNESS: No, you're -- I 18 think you're asking me to explain -- 19 QUESTIONS BY MR. DOVEL: 20 Q. No. No. I'm asking, did you 21 write these words? 22 A. Well, yes, I wrote the words. 23 Of course I wrote the words. 24 Q. Well, it's a very easy answer 25 then, isn't it? Yes?</p> |
| Page 246 | Page 248 |
| <p>1 a finding, and I do understand that 2 that makes it weaker because 3 it's based -- it's just an expert 4 opinion, but that's what I was asked 5 to do, to give expert opinions here. 6 QUESTIONS BY MR. DOVEL: 7 Q. Okay. Well, let's take a look 8 at 782, sir. 9 Do you agree that we've got a 10 woman who is inattentive to doctor's 11 recommendations and does not consider fully 12 potential risks, that's more likely to be 13 someone who has ADHD, right? 14 MS. BROWN: I object to the 15 form of the question and the document. 16 THE WITNESS: Well, I think 17 I've already -- I've already completed 18 this document, so that I just -- 19 you've got two hypothetical people 20 here, and I'm just not comfortable 21 answering that question. 22 QUESTIONS BY MR. DOVEL: 23 Q. Well, sir, it's written right 24 in your report. 25 "Patients with ADHD are more</p> | <p>1 MS. BROWN: I object as 2 argumentative. He's answering your 3 questions, again, about the same -- 4 QUESTIONS BY MR. DOVEL: 5 Q. Is it true, sir, that a patient 6 with ADHD is more likely to take actions 7 without fully considering potential risks and 8 to be inattentive to physician 9 recommendations? Is that true? 10 A. So I'm -- this is not what my 11 report says, okay. My report is -- that 12 sentence that you've got there is not a 13 sentence in my report. 14 Q. Okay. Just answer my question, 15 sir. 16 MS. BROWN: He's doing that. 17 QUESTIONS BY MR. DOVEL: 18 Q. Do you want me to repeat the 19 question? I'll give it to you one more time. 20 Is it true, sir -- 21 MS. BROWN: He already answered 22 it. 23 THE WITNESS: I understand. 24 You're saying, is the second line 25 there -- is true; is that the --</p> |

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| <p>1 essentially the question?</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Is it true, sir, that "Patients</p> <p>4 with ADHD are more likely to take actions</p> <p>5 without fully considering potential risks and</p> <p>6 be inattentive to physician recommendations,"</p> <p>7 Faraone report, page 74?</p> <p>8 Is that a true statement, yes</p> <p>9 or no?</p> <p>10 MS. BROWN: Objection to the</p> <p>11 form.</p> <p>12 THE WITNESS: Yes, what I've</p> <p>13 said there, that's -- yes. That --</p> <p>14 you're reading the sentence on</p> <p>15 page 74?</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. Yeah.</p> <p>18 A. Yes.</p> <p>19 Q. In using, sir, your knowledge</p> <p>20 about ADHD -- withdrawn.</p> <p>21 And based on that knowledge,</p> <p>22 you were willing to speculate about whether</p> <p>23 those women would be more likely to take</p> <p>24 acetaminophen, right?</p> <p>25 MS. BROWN: Objection to the</p> | <p>1 a woman -- if you have ADHD, you're --</p> <p>2 one of the -- one of the -- not</p> <p>3 everybody with ADHD, but some people</p> <p>4 with ADHD are more likely to be</p> <p>5 risk-takers.</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. A risk-taker would be somebody</p> <p>8 who would take aspirin, Advil or Aleve when</p> <p>9 they're pregnant, right? Going against the</p> <p>10 doctor's advice?</p> <p>11 MS. BROWN: I object to the</p> <p>12 form of the question.</p> <p>13 THE WITNESS: Well, let me just</p> <p>14 reread this.</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. Well, let me give you a</p> <p>17 different question, sir.</p> <p>18 A. I do see your point now. I see</p> <p>19 your point now. I do get your point now.</p> <p>20 Let me just --</p> <p>21 Q. Well, are you willing to be a</p> <p>22 truth seeker and just agree with me?</p> <p>23 MS. BROWN: I object to the</p> <p>24 form of the question.</p> <p>25 THE WITNESS: Well, I --</p> |
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| <p>1 form. Argumentative.</p> <p>2 THE WITNESS: I was willing</p> <p>3 to offer my expert opinion about what</p> <p>4 mothers would do, yes.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. Mothers would do with regard to</p> <p>7 taking acetaminophen, right?</p> <p>8 MS. BROWN: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: As an example of</p> <p>11 a potential problem with negative</p> <p>12 controls.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. Right.</p> <p>15 So, sir, if we've got a woman</p> <p>16 who's inattentive to physician</p> <p>17 recommendations, does not consider potential</p> <p>18 risks, is that woman, on average, more likely</p> <p>19 to take aspirin, Advil and Aleve than a woman</p> <p>20 without ADHD?</p> <p>21 MS. BROWN: Objection to the</p> <p>22 same question.</p> <p>23 THE WITNESS: Okay. I -- what</p> <p>24 I'm saying -- okay. Let me -- maybe I</p> <p>25 can -- what I'm saying here is that if</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Or do you want to continue to</p> <p>3 minimize?</p> <p>4 MS. BROWN: I object.</p> <p>5 Let's be polite and</p> <p>6 professional, please. I'm sure you're</p> <p>7 not suggesting he's doing anything but</p> <p>8 truthfully and accurately answering</p> <p>9 your questions.</p> <p>10 MR. DOVEL: I'm not going to</p> <p>11 agree with you there.</p> <p>12 MS. BROWN: Well, I object to</p> <p>13 the way you're treating the witness.</p> <p>14 Let's be professional.</p> <p>15 THE WITNESS: So what I'm</p> <p>16 telling you is that I'm trying to read</p> <p>17 this here and look at this, but at the</p> <p>18 same time you keep repeating questions</p> <p>19 which makes it almost impossible for</p> <p>20 me to kind of process here. What</p> <p>21 you're --</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. Okay. Let me give you a very</p> <p>24 simple question.</p> <p>25 MS. BROWN: You're interrupting</p> |

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| <p style="text-align: right;">Page 253</p> <p>1 him. You're interrupting him. 2 THE WITNESS: You're 3 interrupting. 4 QUESTIONS BY MR. DOVEL: 5 Q. Well, you need to let me give a 6 question to answer then. 7 A. Well, I have a question here. 8 The question is, you know, you're -- you are 9 suggesting that there's something here that 10 is incorrect, and I'm taking that seriously, 11 but I want to read it carefully because I did 12 my -- I did -- as I'm writing this report, I 13 did my darnedest to try to make it, you know, 14 as accurate as possible. If I made a mistake 15 here, I'd like to be able to figure out if 16 that's the case. 17 Q. Let's be really concrete. This 18 is not the chance to go over every part of 19 your report and figure out whether you made 20 mistakes. 21 MS. BROWN: Let's ask a 22 question. 23 QUESTIONS BY MR. DOVEL: 24 Q. I just need answers to my 25 questions.</p> | <p style="text-align: right;">Page 255</p> <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Do you agree? 3 MS. BROWN: Well, let him 4 answer, please. 5 THE WITNESS: Well, as I look 6 at it now, there are -- okay. Yeah, 7 okay. Yeah, interesting. 8 So it -- here when I'm writing 9 about risk, I'm thinking about -- 10 yeah, I do see your point here. I 11 think he would -- I'm trying to 12 recapitulate what I was thinking about 13 in this -- in this sentence here. 14 Here I was -- okay. Hold on a 15 second. So -- okay. So here I'm not 16 comparing women who take acetaminophen 17 versus women who take the other 18 painkillers. 19 I'm talking about taking 20 acetaminophen before and after 21 pregnancy. So there's -- I think we 22 have some common ground in the sense 23 of the different question -- the 24 different issues. 25 So that the -- so the doctor is</p> |
| <p style="text-align: right;">Page 254</p> <p>1 A. I don't want to go over the 2 whole report. I'm just talking about this 3 paragraph here. 4 Q. Let me give you a question, 5 sir. 6 You've got a woman. She's 7 pregnant. She's in the doctor's office. The 8 doctor says, you can take Tylenol, it's fine 9 when you're pregnant, it won't hurt your 10 child, but do not take aspirin, Advil or 11 Aleve, they've got risks. 12 If a woman is inattentive to 13 the doctor's recommendation and potentially 14 engages in risky behaviors, that is, has 15 ADHD, that's the sort of person that's more 16 likely to ignore the doctor's advice to take 17 Tylenol and more likely to take something 18 else than the typical woman, right? 19 MS. BROWN: I object to the 20 form of the question. 21 THE WITNESS: I see your 22 point -- I see your point now. Okay. 23 I see your point. 24 So I have to say -- 25</p> | <p style="text-align: right;">Page 256</p> <p>1 going to tell the woman when -- I 2 mean, again, my -- I have to -- my 3 understanding of the current things 4 that doctors say is that, well, you 5 can take acetaminophen, but limit your 6 dose. 7 So when a mother hears that, 8 right, some mothers will decide, well, 9 they're going to take -- they're -- 10 the doctor thinks it's a problem, then 11 I'm not going to take acetaminophen at 12 all. 13 But if they're more likely to 14 be a risk-taker, they're more likely 15 to take acetaminophen if it were -- 16 and that -- and that might lead to 17 what I'm saying here. 18 Now, you're talking about a 19 potentially different effect, which I 20 just wasn't talking about, because I'm 21 talking about the negative control, 22 before and after, what, prepregnancy 23 and pregnancy. 24 So what you're saying here is 25 that risk-taking would lead to --</p> |

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| <p>1 could lead to this phenomena that 2 you're talking about here. A 3 risk-taker would be more likely to 4 take the risky alternative versus 5 the -- versus acetaminophen in terms 6 of what the doctor is telling them. 7 So I think we're actually both 8 right in this particular instance. 9 QUESTIONS BY MR. DOVEL: 10 Q. I'm going to put a checkmark 11 then next to that one, but let me ask you 12 about what you just said. 13 You assume that they go to the 14 doctor, and they're told to limit their 15 acetaminophen use, right? 16 MS. BROWN: Objection to the -- 17 QUESTIONS BY MR. DOVEL: 18 Q. That was built into what you 19 said, right? You mentioned the word "limit," 20 right? 21 MS. BROWN: I object to the 22 form of the question. 23 THE WITNESS: I was -- what I 24 said to you is that I don't have the 25 exact --</p> | <p>1 acetaminophen intake? 2 A. I have no idea what doctors in 3 general -- 4 MS. BROWN: Hold on. Hold on. 5 THE WITNESS: Okay. 6 MS. BROWN: Because I need to 7 object -- 8 THE WITNESS: Okay. Okay. 9 MS. BROWN: -- to the form of 10 the question, and then you can give 11 that answer. 12 THE WITNESS: I'm sorry. Yeah. 13 MS. BROWN: Go ahead. 14 THE WITNESS: Yeah. 15 So I have no -- I have no idea 16 what doctors in general do. All I'm 17 saying is if we want to address this 18 issue, we can look at the reports from 19 the different professional 20 associations to see what they 21 recommend. 22 QUESTIONS BY MR. DOVEL: 23 Q. Given that you've cited nothing 24 to support this and you don't know in general 25 what doctors do, would you agree that</p> |
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| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Whatever the exact words are. 3 A. -- language the doctors say. 4 Does somebody have them here? Can we look at 5 the -- 6 Q. Yeah. There are -- 7 A. -- their reports? 8 Q. -- no words in the US like 9 that. That's a European standard. 10 In the US, doctors don't tell 11 them to limit. They say, take as much as you 12 want. 13 MS. BROWN: Objection. 14 Objection, let's ask a question. 15 QUESTIONS BY MR. DOVEL: 16 Q. Were you aware of that? 17 MS. BROWN: I object to the 18 form of that question. 19 THE WITNESS: I think we'd have 20 to pull out all of the recommendations 21 from the different associations to get 22 a sense of what is and isn't said. 23 QUESTIONS BY MR. DOVEL: 24 Q. Were you aware that doctors in 25 general do not tell women to limit their</p> | <p>1 there's -- you've got no basis to conclude 2 that patients with -- who are taking 3 acetaminophen -- or that women who take 4 acetaminophen during pregnancy are more 5 likely -- withdrawn. 6 You have no basis to conclude 7 that women with ADHD are going to take more 8 acetaminophen during pregnancy than outside 9 of pregnancy? 10 MS. BROWN: Objection to the 11 form of the question. 12 THE WITNESS: I don't agree 13 with the no basis comment there. As I 14 said, the basis was my expert 15 knowledge about ADHD that has accrued 16 over a period of decades, including 17 knowledge about adult ADHD. 18 QUESTIONS BY MR. DOVEL: 19 Q. Well, it was your knowledge 20 that you said that women are going to -- with 21 ADHD are going to take more acetaminophen 22 than other women, right? 23 MS. BROWN: Objection to the 24 form. 25</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. So let me back up a second.</p> <p>3 I want to talk about a</p> <p>4 different comparison with you.</p> <p>5 MS. BROWN: Counsel, can we</p> <p>6 take our lunch break before we go into</p> <p>7 something different?</p> <p>8 MR. DOVEL: I'm just finishing</p> <p>9 this up.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. Sir, I've got another question</p> <p>12 for you. I need you to pay attention. I've</p> <p>13 withdrawn that one.</p> <p>14 Okay?</p> <p>15 A. Okay. I'm good.</p> <p>16 Q. Women with ADHD who take</p> <p>17 acetaminophen when they're pregnant versus</p> <p>18 women with ADHD who take acetaminophen when</p> <p>19 they're not pregnant, do you have any basis</p> <p>20 to conclude that there's a difference there?</p> <p>21 A. The basis I have is what I told</p> <p>22 you. It was my expert opinion that that's</p> <p>23 where these words come from. There's no --</p> <p>24 that's why there's no citation.</p> <p>25 And when I take a statement</p> | <p>1 when they're pregnant than when they're not</p> <p>2 pregnant?</p> <p>3 MS. BROWN: Object to the form</p> <p>4 of the question.</p> <p>5 THE WITNESS: So it is, again,</p> <p>6 just an opinion. There's no data that</p> <p>7 I know of, on this topic. It's just</p> <p>8 an opinion.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. And is it that they're going to</p> <p>11 suddenly start taking more when they get</p> <p>12 pregnant?</p> <p>13 MS. BROWN: Objection to the</p> <p>14 form.</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. Or less?</p> <p>17 MS. BROWN: Same objection.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Or do you have no idea?</p> <p>20 MS. BROWN: Objection to the</p> <p>21 form.</p> <p>22 THE WITNESS: So I'm trying to</p> <p>23 recreate the reasoning behind this</p> <p>24 when I wrote the report. That's why I</p> <p>25 paused for a second.</p> |
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| <p>1 like this where there's no citation, it means</p> <p>2 this is -- this is my expert opinion.</p> <p>3 Q. But, sir, even assuming that</p> <p>4 this were right, why would that mean that a</p> <p>5 woman with ADHD would take less acetaminophen</p> <p>6 when they're not pregnant? Aren't they going</p> <p>7 to take the same either way?</p> <p>8 MS. BROWN: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: So part of the</p> <p>11 reasoning here is that -- well, again,</p> <p>12 you know, I would -- do we have -- I</p> <p>13 guess I'm not allowed to look at</p> <p>14 the -- these reports from associations</p> <p>15 and so forth, what the recommendations</p> <p>16 are?</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. Well, I just need an answer to</p> <p>19 this question, sir.</p> <p>20 If we've got a woman with ADHD</p> <p>21 and they take acetaminophen when they're</p> <p>22 pregnant, do you have any -- withdrawn.</p> <p>23 Do you have any basis for</p> <p>24 concluding that the consumption rate of</p> <p>25 acetaminophen by women with ADHD is different</p> | <p>1 The reasoning comes roughly as</p> <p>2 this, okay? Women who are pregnant --</p> <p>3 and I'm not -- not saying I'm an</p> <p>4 expert in this area, but I just happen</p> <p>5 to know from having three children of</p> <p>6 my own. Women who are pregnant are</p> <p>7 told to avoid lots of things by their</p> <p>8 doctors.</p> <p>9 Now, my recollection from some</p> <p>10 of the things like -- you know, even</p> <p>11 the Bauer consensus statement and so</p> <p>12 forth recommends limiting the dose and</p> <p>13 so forth. There's some -- there's a</p> <p>14 lot of stuff out there about</p> <p>15 recommendations about limiting amount</p> <p>16 of acetaminophen -- the amount of</p> <p>17 acetaminophen. That someone who is</p> <p>18 more likely to take risks is more</p> <p>19 likely to ignore that.</p> <p>20 And they're more likely to do</p> <p>21 that -- the risky part, of course, is</p> <p>22 during pregnancy. They're more likely</p> <p>23 to ignore that.</p> <p>24 And so that would -- if that --</p> <p>25 if that occurs, it would increase</p> |

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| <p>1 their likelihood of taking 2 acetaminophen during pregnancy because 3 they're risk-takers. And it would -- 4 it would differ because when you're 5 outside of pregnancy, then there's -- 6 you know, there's no risks. There's 7 no -- no one's talking to you about 8 these -- any kind of risk being 9 involved. 10 It is -- this is just my -- 11 just some reasoning, trying to make 12 the point that these -- there are 13 these time-varying confounds that make 14 these, you know, negative controls 15 difficult to interpret. 16 And it -- 17 MR. DOVEL: Let's take our 18 lunch break. 19 VIDEOGRAPHER: The time right 20 now is 1:05 p.m. We're off the 21 record. 22 (Off the record at 1:05 p.m.) 23 VIDEOGRAPHER: The time right 24 now is 1:50 p.m. We are back on the 25 record.</p> | <p>1 for a behavioral geneticist. I don't 2 know that that would be possible. I'm 3 not saying it's not possible. I'm 4 just saying I don't know that it would 5 be possible. 6 QUESTIONS BY MR. DOVEL: 7 Q. Let me give you an example of 8 something you might be able to comment on. 9 You understand that height in 10 humans is highly heritable, above 80 percent? 11 A. Yes. 12 Q. Would you agree that someone's 13 height as an adult is always dependent on 14 their environmental factors, such as their 15 nutrition? 16 MS. BROWN: I object to the 17 form of the question. 18 THE WITNESS: Again, I'm not an 19 expert on height, what regulates 20 height, but what you said sounds 21 commonsensical, but I -- you know, I 22 just don't know enough about the -- 23 how -- you know, how -- that's formed, 24 whether that's -- whether that's true 25 or not.</p> |
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| <p>1 QUESTIONS BY MR. DOVEL: 2 Q. If a trait has high 3 heritability, say in excess of 80 percent, is 4 it still the case that environmental 5 influences can play a role in 100 percent of 6 humans? 7 MS. BROWN: Object to the form. 8 THE WITNESS: Oh, that's a good 9 question. I've never heard it phrased 10 that way. Let me think about that. 11 So if the trait has high 12 heritability, can an environmental 13 event -- so maybe if I can just 14 rephrase it a little bit. 15 Let's say, for example, ADHD's 16 heritability is 76 percent. Does that 17 mean is it possible that an 18 environmental event could affect 19 everybody with ADHD? 20 QUESTIONS BY MR. DOVEL: 21 Q. Yes. 22 MS. BROWN: And I object to the 23 form of that. 24 THE WITNESS: Yeah, I don't 25 know. That's -- would be a question</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. And if we have identical twins, 3 one member of this identical twin pair has 4 ADHD, the chances that the other one does is 5 just 50 percent, right? 6 MS. BROWN: Objection to the 7 form. 8 THE WITNESS: That's what 9 the -- I think the Stevenson study 10 showed. 11 QUESTIONS BY MR. DOVEL: 12 Q. And that tell us that 13 environmental risk factors must play a role 14 in the causation of ADHD, right? 15 MS. BROWN: Objection to the 16 form. 17 THE WITNESS: That's very 18 clear, from heritability too, yes, 19 that there's no -- I've said that 20 multiple times in things that I've 21 written. Absolutely. 22 QUESTIONS BY MR. DOVEL: 23 Q. It's never just genetics alone; 24 it's genes, environment and how they interact 25 to cause ADHD, right?</p> |

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| <p>1 MS. BROWN: Objection to the 2 form. 3 THE WITNESS: Well, what we 4 don't know for sure is it's never 5 genetics alone. So we just don't 6 know. It's -- there's given -- given 7 that heritability is high, it's quite 8 possible that there are some cases 9 of -- I'll call it, you know, common 10 variant ADHD, meaning ADHD caused by 11 the common risk variants, that are 12 only due to the genetic risk for ADHD. 13 And others are a mix of 14 gene-environment interaction and that 15 they're -- well, there are some cases 16 of environmentally induced ADHD, like 17 the traumatic brain injury would be an 18 example of that. 19 It's -- well, we -- the rare 20 variant -- there are also the rare 21 variant cases which are less 22 well-described in the ADHD world, but 23 it's conceivable that there's some 24 rare variants that can cause ADHD 25 without an environmental impact.</p> | <p>1 variants combine with and interact with 2 environmental risk factors to create the 3 pathophysiology of ADHD? 4 MS. BROWN: Objection to the 5 form. 6 THE WITNESS: That is one of my 7 current hypotheses. 8 QUESTIONS BY MR. DOVEL: 9 Q. In your view it's -- based on 10 the evidence you've seen, it's likely, more 11 likely than not, that that's how ADHD is 12 caused, right? 13 MS. BROWN: Object to the form. 14 THE WITNESS: Again, I'm 15 talking about what I call common 16 variant ADHD, which is probably the 17 most ADHD. And also clarifying that 18 we don't -- we don't know what mix of 19 genes and genetic ris -- genetic 20 causes, and this unknown environmental 21 cases, we don't know what the exact 22 mix is needed in any given individual, 23 except we do know that the genetic -- 24 there are more genetic causes 25 roughly -- you know, accounting for</p> |
| Page 270 | Page 272 |
| <p>1 But that's -- I think the jury 2 is still out on that one. 3 QUESTIONS BY MR. DOVEL: 4 Q. Now, the multi-focal -- 5 withdrawn. 6 The multifactorial model of 7 ADHD causation is one in which many genetic 8 and environmental factors combine to cause 9 ADHD, right? 10 MS. BROWN: Object to the form. 11 THE WITNESS: Correct. 12 QUESTIONS BY MR. DOVEL: 13 Q. And you agree that that's 14 likely the best explanation for the cause of 15 ADHD, is this multi-factorial model in which 16 multiple genetic and risk -- environmental 17 risk factors combine? 18 MS. BROWN: Objection to the 19 form. 20 THE WITNESS: So, yes, the 21 multi -- that's my common hypothesis 22 about the etiology of ADHD; that it is 23 as you stated it. 24 QUESTIONS BY MR. DOVEL: 25 Q. Under that theory, genetic risk</p> | <p>1 76 percent of the variants versus the 2 environmental causes. 3 But the exact mix in any 4 individual and how that's distributed 5 in the population is -- it's unknown 6 at this point because we don't have a 7 good handle on the environmental -- on 8 the environmental causes. 9 (Faraone Exhibit 702 marked for 10 identification.) 11 QUESTIONS BY MR. DOVEL: 12 Q. I am going to mark as 13 Exhibit 702 your original report with all of 14 the exhibits. Two copies. 15 I'm going to place in front of 16 you a portion of the Federal Rules of Civil 17 Procedure. 18 I'm not going to mark this as 19 an exhibit. It's just for the purpose of 20 having you focus on part of this language 21 here. It's about expert reports. 22 A. Uh-huh. 23 Q. One of the things the expert 24 report has to contain is a complete statement 25 of all opinions the witness will express and</p> |

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| <p>1 the basis and reasons for them.</p> <p>2 Does your expert report, which</p> <p>3 is Exhibit 702, the original report, along</p> <p>4 with Exhibit 701, your amended report,</p> <p>5 contain a complete statement of your</p> <p>6 opinions?</p> <p>7 A. I believe it does.</p> <p>8 Q. Did you at any point, as you</p> <p>9 were working on your expert report, arrive at</p> <p>10 an opinion and say, nope, I'm not going to</p> <p>11 write it down, I'm going to withhold this</p> <p>12 one, not put it in here?</p> <p>13 MS. BROWN: Objection to the</p> <p>14 form of the question.</p> <p>15 THE WITNESS: Did not put in an</p> <p>16 opinion? I'm pretty sure that's not</p> <p>17 the case. When you say "an opinion,"</p> <p>18 I mean, the main opinion here is about</p> <p>19 causality, and that's -- nothing about</p> <p>20 that was changed.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Your report is also required to</p> <p>23 contain a complete basis and reasons for your</p> <p>24 opinions.</p> <p>25 Do your expert reports,</p> | <p>1 Now, there's two sides to this.</p> <p>2 One of them has some numbers on it, the other</p> <p>3 one doesn't. Let's start with the one</p> <p>4 without the numbers.</p> <p>5 Do you recognize this as a</p> <p>6 schematic view of how genes and environment</p> <p>7 combine to cause ADHD?</p> <p>8 A. I recognize this as something I</p> <p>9 have, I think, presented in the slides for</p> <p>10 sure. Slide presentations.</p> <p>11 Q. As a view of how genes and</p> <p>12 environment combine to cause ADHD?</p> <p>13 MS. BROWN: Hold on.</p> <p>14 Objection to the form.</p> <p>15 THE WITNESS: It's essentially</p> <p>16 a kind of a cartoon, if you will,</p> <p>17 of -- when I'm talking to people about</p> <p>18 the genetics -- when I talk to people</p> <p>19 about etiology of ADHD and I'm talking</p> <p>20 about these issues we've just been</p> <p>21 talking about, how genes and the</p> <p>22 environment combine, this is kind of a</p> <p>23 cartoon to give -- to let people know</p> <p>24 how I think about it, which, of</p> <p>25 course, I spend some time talking</p> |
| Page 274 | Page 276 |
| <p>1 Exhibit 701 and 702, contain a complete</p> <p>2 statement of the basis and reasons for your</p> <p>3 opinions?</p> <p>4 A. Yes.</p> <p>5 Q. Did you at any point, when</p> <p>6 working on your reports, come across a basis</p> <p>7 or reasons that you thought would support</p> <p>8 your opinions and decide to withhold it and</p> <p>9 not put it in your report?</p> <p>10 MS. BROWN: I object to the</p> <p>11 form of the question.</p> <p>12 THE WITNESS: Did I decide to</p> <p>13 withhold anything? No.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. All your bases and reasons are</p> <p>16 in your expert reports, right?</p> <p>17 MS. BROWN: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: Yeah, that is...</p> <p>20 (Faraone Exhibit 714 marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. Let's mark as Exhibit 714 a</p> <p>24 schematic view of how genes and environment</p> <p>25 combine to cause ADHD.</p> | <p>1 about as well.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Well, cartoon, are you trying</p> <p>4 to minimize what's depicted here?</p> <p>5 A. It's a --</p> <p>6 MS. BROWN: Well, hold on.</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. I just want to know, are you</p> <p>9 trying to minimize, yes or no?</p> <p>10 MS. BROWN: Okay. Let me just</p> <p>11 object -- I object -- hold on. I</p> <p>12 object to the form of that question.</p> <p>13 THE WITNESS: Okay.</p> <p>14 I'm going to explain to you</p> <p>15 what I mean by cartoon. So maybe</p> <p>16 cartoon is not the right word.</p> <p>17 It's not actually a graph of</p> <p>18 data. It's not -- it's not based on</p> <p>19 any quantitative assessment. It's</p> <p>20 simply a schematic that is saying that</p> <p>21 you can have people with high</p> <p>22 environmental risk, low genetic --</p> <p>23 high genetic pre -- low risk -- high</p> <p>24 genetic risk, low genetic risk, and</p> <p>25 usually -- you don't have them here.</p> |

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| <p>1 Usually there's labels of those 2 three -- on those three slices that 3 are different colors. 4 Not this one, but then I would 5 probably have discussed that either -- 6 if this is in a document -- is this 7 from a document or a slide? 8 QUESTIONS BY MR. DOVEL: 9 Q. I've taken this one from a 10 document. 11 A. Document. So perhaps those are 12 described in the document. Can we see the 13 document? 14 Q. We're going to get to that in a 15 second, yeah. 16 Let's turn it over, and I'd 17 like to use the ELMO here. 18 A. Yeah. 19 Q. Here I've added some numbers, 1 20 through 9, along both scale, just so we can 21 have some points that we can talk about. 22 These are just arbitrary numbers. 23 Now, as I understand how this 24 works -- 25 A. I'm sorry, just to clarify,</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Here, let me give you a 3 different question, if you don't want to 4 answer this one. 5 Would you agree, sir, the way 6 this graphic is depicted the area in white is 7 designed to indicate these are folks that do 8 not have an ADHD diagnosis, right? 9 MS. BROWN: I object to the 10 form of these questions. 11 THE WITNESS: Okay. So the 12 different bands are typically meant to 13 indicate changes in severity of 14 ADHD -- of the ADHD diagnosis. 15 I don't know exactly how these 16 ones are particularly labeled because 17 I don't see the labels. And then, 18 yes, the area in white is meant to 19 signify people that don't have ADHD, 20 not in any -- the proportions are not 21 in any way meaningful here. It's just 22 a schematic that's used for 23 discussion. 24 So it's not -- for example, the 25 prevalence of ADHD, you can see that,</p> |
| Page 278 | Page 280 |
| <p>1 those are your numbers, not my numbers? 2 Q. Yes. 3 A. Okay. Good. I didn't think I 4 had numbers there. Okay. Thank you. 5 Q. Now, if we look at this first 6 line here, this would indicate -- this first 7 band, what's sometimes called subthreshold 8 ADHD, right? 9 MS. BROWN: Objection to the 10 form. 11 THE WITNESS: I think you've 12 removed the -- correct. I think 13 you've actually removed some things 14 from this graphic; is that correct? 15 QUESTIONS BY MR. DOVEL: 16 Q. That's right. 17 The labels for the bands. This 18 would be called subthreshold ADHD, right? 19 A. Can we have -- can I see -- can 20 I see the graphic that has the labels on it? 21 Q. I'm happy to show that to you. 22 I just want to know do you -- if you don't 23 recall, say "I don't recall." That's fine. 24 MS. BROWN: Objection to the 25 form.</p> | <p>1 you know, they colored in circles, 2 this -- you know, that's much more 3 than the prevalence of ADHD would be. 4 It's only 5 percent of the population. 5 QUESTIONS BY MR. DOVEL: 6 Q. This diagram is not to scale. 7 A. It's not to any particular 8 scale. 9 Q. Right. 10 A. It's just for discussion 11 purposes. 12 Q. And what this is -- the way we 13 read this diagram is the farther out you get 14 into this darker area, the more ADHD symptoms 15 you have? 16 MS. BROWN: Objection to the 17 form. 18 THE WITNESS: Correct. Yes. 19 Yeah, I'm sorry. Let me look at this 20 thing. 21 QUESTIONS BY MR. DOVEL: 22 Q. And if we are farther -- the 23 farthest-out level, that's what we sometimes 24 are labeled as persistent ADHD; that is, ADHD 25 that persists into adulthood.</p> |

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| <p>1 A. Ah. Was that the label I used 2 in this particular case? 3 Q. I believe it was, yes. 4 A. That does make sense. So this 5 would be persistent ADHD, could be persistent 6 ADHD, not persistent in subthresholds. Maybe 7 those were labels. 8 Q. In fact, if you take a look at 9 Exhibit 780, the -- no, 780 -- 10 A. Like the World Federation 11 Guide? 12 Q. Yes. 13 A. Oh, yeah. Where's that? 14 Q. Page 13. 15 A. All right. That's the World 16 Federation. It's got a -- 17 MS. BROWN: Colorful -- 18 THE WITNESS: -- colorful 19 graphic on it. 20 MS. BROWN: Let's see if we can 21 find that. 22 THE WITNESS: I'm pretty proud 23 of that. It's translated into, like, 24 I don't know, a bunch of different 25 languages.</p> | <p>1 right here. This right here. 2 A. That's correct. 3 Oh, well -- okay. So there's a 4 nuance here that you can have subthreshold 5 ADHD and still get a DSM diagnosis. There 6 are -- the way the DSM works is that they 7 have these different diagnostic code 8 categories. So when we talk about 9 subthreshold cases, we're talking about 10 people who come into the clinic and they're 11 experiencing lots of problems and one -- you 12 go through the diagnostic workup for them, 13 and maybe, you know, they don't -- they have 14 five symptoms of ADHD, let's say. Or they 15 could even have five inattentive and five 16 hyperactive-impulsive and they still don't 17 meet criteria, even though they have ten 18 symptoms. 19 In that case, there's -- you 20 can actually diagnose them with ADHD. It's 21 just a different diagnostic code. I forget 22 what it's called. It's not actually called 23 subthresholds. It's got another name. 24 So there -- but -- so anyway, 25 that's -- I wanted to make that -- make it</p> |
| Page 282 | Page 284 |
| <p>1 MS. BROWN: Here we are. 2 THE WITNESS: Oh, here we go. 3 Thank you. 4 MS. BROWN: All right. You 5 took your paperclip off so just make 6 sure you -- we have all of the pages. 7 QUESTIONS BY MR. DOVEL: 8 Q. Take a look at page 13. 9 A. Oh, yeah, here we go. Yes. 10 Okay. 11 Q. So the darker area is what's 12 labeled as persistent -- 13 A. Yes. 14 Q. -- ADHD? 15 A. Yes. 16 Q. The next area would be 17 remitting ADHD? 18 A. That's correct. 19 Q. And this is subthreshold cases? 20 A. That's correct. 21 Q. Now, if you take a look at -- 22 I'm going to put an arrow here. This line 23 right here, this is -- 24 A. Sorry. 25 Q. -- the line for ADHD diagnosis</p> | <p>1 clear that that's the case. 2 Q. Okay. So ADHD diagnosis could 3 even come down here for some of the 4 subthresholds? 5 A. Yeah, exactly. Some people in 6 that category will end up -- will end up 7 getting a diagnosis. 8 Q. With a formal DSM-5 diagnosis 9 for most folks is going to be at this line 10 here when we cross past subthreshold? 11 A. Right. And for -- when we talk 12 about research studies and so forth, 13 informally, almost everybody just -- does not 14 include subthreshold cases in a researched 15 study. 16 Q. Now, the way the environmental 17 and genetic risks come together is that 18 there's -- people have a certain set of genes 19 that they're born with, common variants, 20 given the genetic risk for ADHD? 21 A. Uh-huh. 22 Q. In addition they have various 23 environmental exposures. For example, 24 exposures in utero when they're a fetus, and 25 those combine to produce different levels of</p> |

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| <p style="text-align: right;">Page 285</p> <p>1 ADHD symptoms; is that right?</p> <p>2 A. Well, that's -- this is what</p> <p>3 the hypothesis they were -- that is being</p> <p>4 presented here. We don't know -- we don't</p> <p>5 know what the environmental causes are. We</p> <p>6 don't know the mix of them, except that</p> <p>7 there's -- they are more ADHD. Genetic risks</p> <p>8 are greater, but, yes, this is --</p> <p>9 Q. Is it fair to call this a</p> <p>10 schematic view of how genes and environment</p> <p>11 combine to cause ADHD?</p> <p>12 A. Yeah.</p> <p>13 MS. BROWN: Objection to the</p> <p>14 form.</p> <p>15 THE WITNESS: I just did.</p> <p>16 I'm sorry. Yeah.</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. And if we -- just to use some</p> <p>19 of these numbers. For example, suppose</p> <p>20 somebody had fairly high genetic</p> <p>21 predisposition. It was a 6 in our example</p> <p>22 here --</p> <p>23 A. 6.</p> <p>24 Q. -- and the environmental risk</p> <p>25 was 3, they would be somebody who would not</p> | <p style="text-align: right;">Page 287</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. And that's common for most</p> <p>3 environmental risk factors; that is -- in</p> <p>4 fact, for most -- for most risk factors it's</p> <p>5 rare to find one that's sufficient all by</p> <p>6 itself, right?</p> <p>7 It requires usually multiple</p> <p>8 risk factors to cause ADHD, right?</p> <p>9 MS. BROWN: I object to the</p> <p>10 form of the question.</p> <p>11 THE WITNESS: I -- yeah, I can</p> <p>12 agree to that only if you understand</p> <p>13 what I'm saying here is that this</p> <p>14 is -- this is a hypothesis, right,</p> <p>15 which I -- you know, I hold, and which</p> <p>16 is why I present it here and</p> <p>17 elsewhere, that environmental risks</p> <p>18 that are reported -- well, it's -- the</p> <p>19 label of environmental risk is</p> <p>20 referring to the environmental</p> <p>21 correlates that we know of.</p> <p>22 You know, as you know, what</p> <p>23 I've said in my writings is that we</p> <p>24 don't have environmental causes of</p> <p>25 ADHD. But we do have -- that said,</p> |
| <p style="text-align: right;">Page 286</p> <p>1 come down with ADHD?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: That's exactly</p> <p>5 what the schematic would mean there,</p> <p>6 yes.</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. It would take greater</p> <p>9 environmental risk factors before they would</p> <p>10 get ADHD?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form.</p> <p>13 THE WITNESS: Correct.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. In that case, we would say that</p> <p>16 these additional environmental risk factors</p> <p>17 are actually necessary to causing ADHD,</p> <p>18 right?</p> <p>19 MS. BROWN: I object to the</p> <p>20 form of these questions.</p> <p>21 THE WITNESS: Yeah. For these</p> <p>22 people, we would kind of describe it</p> <p>23 as a necessary but not sufficient</p> <p>24 cause, yeah.</p> <p>25</p> | <p style="text-align: right;">Page 288</p> <p>1 this is how I think -- this is a</p> <p>2 schematic of how I think in many cases</p> <p>3 of ADHD that could combine.</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. This World Federation Guide,</p> <p>6 this was published by the World Federation of</p> <p>7 ADHD. It's not simply your opinion, right?</p> <p>8 A. Well, it's actually published</p> <p>9 by -- who's the publish -- it's not -- it's</p> <p>10 published by -- what's the company called? I</p> <p>11 think it was a publication -- it has a funny</p> <p>12 kind of co -- it's a co-publication with a</p> <p>13 Brazilian, yeah, Artmed. It's actually</p> <p>14 co-published between Artmed, which is a</p> <p>15 Brazilian publishing house, and World</p> <p>16 Federation.</p> <p>17 The book was actually conceived</p> <p>18 by a Luis Augusto Rohde, who's from Brazil,</p> <p>19 and he arranged the deal with this publisher</p> <p>20 to potentially publish the book in Brazil in</p> <p>21 Portuguese and then let the World Federation</p> <p>22 use it -- published on their website and --</p> <p>23 Q. Well, to be clear, this is not</p> <p>24 merely just your hypothesis that's presented</p> <p>25 here. This is the hypothesis that's</p> |

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| <p>1 acknowledged to be the most likely hypothesis 2 by the World Federation of ADHD. 3 A. No, no, no. No, no, no. 4 MS. BROWN: Hold on. Hold on. 5 I object to the form of the question. 6 THE WITNESS: Yeah. All right. 7 Give you a chance. 8 MS. BROWN: Go ahead. 9 THE WITNESS: That's not 10 correct. It's -- it's an edited -- 11 it's an edited volume, and the 12 chapters in the volume are the work 13 product of the individuals of the 14 authors. So it's like any other -- 15 it's like any other edited book. 16 What's expressed in the chapter 17 is not the view of -- certainly not 18 the -- it's not the view of the 19 publisher or the World Federation. 20 It's -- the World Federation -- 21 yeah. That's -- I think I'll stop 22 there. That sentence says it. 23 QUESTIONS BY MR. DOVEL: 24 Q. Well, do you agree that it's 25 the scientific consensus that most cases of</p> | <p>1 that's designed to be somewhere in the middle 2 of the subthreshold band. 3 Do you see that? 4 A. Yes, I do. 5 Q. To cross over the ADHD 6 diagnosis, they're going to need either to 7 have been exposed to greater environmental 8 risk or have different genetic 9 predisposition -- greater genetic 10 predisposition, right? 11 MS. BROWN: Objection to the 12 form. 13 THE WITNESS: Correct. 14 QUESTIONS BY MR. DOVEL: 15 Q. Now, if it's the case that 16 ADHD -- withdrawn. 17 If it were the case that 18 acetaminophen were an environmental risk 19 factor in the cause of ADHD and somebody was 20 exposed to substantial ADD -- acetaminophen 21 during -- when they were a fetus, that was 22 able to move their environmental risk from 23 here a 5 up to a 6, that would then cross 24 them over into the ADHD diagnosis area, and 25 I'll label that B.</p> |
| Page 290 | Page 292 |
| <p>1 ADHD are caused by a combination of 2 environmental and genetic risk factors? 3 MS. BROWN: Objection to the 4 form. 5 THE WITNESS: I would think 6 that the consensus -- that's a good 7 question. I'm trying to remember if 8 we put it in the consensus statement, 9 actually. 10 QUESTIONS BY MR. DOVEL: 11 Q. Well, we'll get to it. 12 A. I would think -- 13 Q. Yes, you did. 14 A. I would think -- I would think 15 that most of my colleagues would -- wouldn't 16 have -- I mean, they might not like this 17 figure, per se, but there's a statement that 18 both environment and genes are involved in 19 the etiology. They would certainly agree to 20 that. 21 Q. Now, is it the case -- let's 22 assume we have someone who has a genetic risk 23 that's pretty high of 6 here, environmental 24 risk of 5, that person -- I'll put a little 25 dot there and call it A, approximately. And</p> | <p>1 MS. BROWN: I object to the 2 form of the question. 3 THE WITNESS: Okay. So here's 4 what we don't know. We're starting to 5 get to the category of things we don't 6 know. 7 We don't know -- in the 8 multifactorial model, you know, we 9 estimate there are probably 7,000 10 genetic risk variants, common risk 11 variants. We don't know how many, you 12 know, environmental causes will 13 eventually be discovered. Let's say, 14 you know, 50 years from now, we'll 15 have -- you know, we'll know this. 16 If there are 7,000, the answer 17 to the question is a lot different 18 than if there are five. We just -- we 19 just don't know. 20 What we can say is that the 21 environmental -- just like the genomic 22 risk, the environmental risk is going 23 to move people as you suggested, but 24 maybe not that far. We just don't -- 25 we just don't know.</p> |

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| <p>1 And, I mean, that's -- we just 2 don't know. 3 QUESTIONS BY MR. DOVEL: 4 Q. Yeah. We don't have a scale in 5 which we could measure right now for a given 6 environmental or genetic risk how far it 7 moves them up the scale of likelihood, right? 8 A. For the genetic risks -- well, 9 we don't have any environmental causes. We 10 have genetic causes. So we can, to some 11 degree, for example, with the polygenic risk 12 score get a sense of how -- how much 13 someone's moving up the risk ladder based 14 upon the number of variants they have. 15 So, for example, if you plot 16 somebody's polygenic risk score against 17 their per -- like say, you just go out into 18 the population, and you get DNA from a bunch 19 of people, and you plot their probability of 20 having ADHD against their polygenic risk, 21 you'll see a very nice linear relationship, 22 that people with high polygenic risk have a 23 higher likelihood that they can have ADHD. 24 So we have a general sense of 25 that for the genome, but we just don't know</p> | <p>1 by young adulthood, they're among the 2 two-thirds where it's -- it's gone 3 away. 4 There's some cases that persist 5 of ADHD that are not necessarily very 6 severe, but -- I mean, they're severe 7 enough to meet diagnostic thresholds, 8 but it could be clinically mild, but 9 that level of clinical severity, in 10 this case mild, might just be -- might 11 persist. 12 So in this case we're talking 13 not about severity, but about the 14 per -- it's -- about persistence. 15 QUESTIONS BY MR. DOVEL: 16 Q. Well, if we're talking about 17 going from symptoms that are below 18 subthreshold into a diagnosis, we're talking 19 about the severity of symptoms, right? 20 A. From below -- yeah. From below 21 subthreshold into anyone that's -- meets case 22 category, yes. Because in order to meet 23 diagnostic criteria, you need to show 24 impairment -- you know, real life 25 impairments, something is causing you</p> |
| Page 294 | Page 296 |
| <p>1 it all for the -- for the -- for the 2 environmental causes that are yet -- as of 3 yet undiscovered. 4 Q. When someone is exposed to 5 greater environmental risk, that also 6 increases the severity of symptoms, right? 7 MS. BROWN: I object to the 8 form of the question. 9 THE WITNESS: Actually, we 10 don't know that. We just don't know. 11 I mean, in the sense that if -- well, 12 in the sense that if -- if -- if -- if 13 this is correct and if genomic and 14 environmental -- environmental risks 15 are moving people more towards a -- 16 well, here's -- it's kind of a little 17 bit of a difficulty with severity. 18 It's moving it into -- it's 19 moving it from subthreshold to 20 remitting to persistent. It's not 21 necessarily severity. 22 So someone could have remitting 23 ADHD that was very severe in 24 childhood, and then they're one of the 25 lucky ones, and by young -- you know,</p> | <p>1 distress, disability in your life in at least 2 two different settings. 3 Q. Does exposures to increased 4 environmental risk factors increase the level 5 of symptoms? 6 MS. BROWN: I object to the 7 form of the question. 8 THE WITNESS: It's a great 9 question. I'm trying to think if 10 there's any data on that. I don't -- 11 I don't recall -- sitting here, I just 12 don't recall any data on that. 13 QUESTIONS BY MR. DOVEL: 14 Q. If we've got a combin -- if 15 somebody is -- withdrawn. 16 If somebody's experiencing a 17 combination of genetic risk and also 18 environmental risk, does that combination 19 determine the severity of their symptoms? 20 MS. BROWN: I object to the 21 form of the question. 22 THE WITNESS: If I had to form 23 a hypothesis about it, I would 24 hypothesize that the more -- as more 25 causes pile up, you would experience</p> |

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| <p>1 more severity. But it's -- it would 2 just be a hypothesis. 3 I don't know that I -- I just 4 don't know any data on that issue. 5 I'm also trying to think about 6 whether we even have that data in the 7 genomic world. 8 I just also want to mention, 9 make a point, just to clarify, that 10 severity is sometimes -- it's -- one 11 of the reasons I'm kind of hesitating 12 a little here is that severity is a -- 13 is a -- it's not a simple construct, 14 as -- we've got one-dimensional 15 construct. 16 So, for example, somebody can 17 have lots of ADHD symptoms. You can 18 talk about severity as number of 19 symptoms, but severity is also -- can 20 be talked about as the degree to which 21 this -- the disorder is impair -- is 22 impairing somebody in their everyday 23 life. 24 So you can, for example, have 25 people who are subthreshold in the</p> | <p>1 THE WITNESS: Yes. So this -- 2 yeah, this chapter is about 3 environmental risk factors, and as I 4 said before, risk factors are -- the 5 ones we know now are -- none of -- 6 none of them have been justified as 7 actual causes. They're risk factors, 8 meaning correlates, of ADHD. 9 QUESTIONS BY MR. DOVEL: 10 Q. Well, my question was more 11 specific about this language. 12 A. Yeah. 13 Q. When you write here, 14 "Environmental causes of ADHD," are you 15 referring to the environmental risk factors 16 that can combine with genetic risk to cause 17 ADHD? 18 MS. BROWN: Objection to the 19 form of the question. 20 THE WITNESS: So it just means 21 that the section -- we have a section 22 on genetic causes, and there's a 23 section on environmental causes, and 24 that's the only -- that just signifies 25 the heading of the -- of the section</p> |
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| <p>1 sense of they have fewer symptoms, but 2 for some reasons, they're 3 experiencing -- they're -- they 4 are very severe in terms of their -- 5 what's happened to them in everyday 6 life. 7 QUESTIONS BY MR. DOVEL: 8 Q. All right. Let's take a look 9 at Exhibit 780, your guide. Get out the 10 ELMO. 11 A. This is the guide again. 12 Q. Page -- 13 A. Okay. Page -- 14 Q. Page 8. 15 A. Let's see. Page 8. I'm there. 16 Q. Page 8 there's a chapter -- 17 withdrawn. 18 On page 8 there's a section 19 titled "Environmental Causes of ADHD," right? 20 By environmental causes, do you 21 mean the environmental risk factors, that 22 when combined with genetic risk, can cause 23 ADHD? 24 MS. BROWN: Objection to the 25 form.</p> | <p>1 that we're in here. 2 QUESTIONS BY MR. DOVEL: 3 Q. Well, I know it's the heading, 4 but I'm just trying to interpret the meaning 5 of it. 6 By environmental causes, are 7 you referring to the environmental risk 8 factors that can combine to result in ADHD? 9 A. Hold on. 10 MS. BROWN: Objection to the 11 form of the question. 12 THE WITNESS: I think I can 13 clarify that, if I can read this for a 14 little bit here. 15 I'm sorry. I'm sorry. It's 16 my -- these pages got mixed up here, 17 so I'm -- okay. 18 Yeah. So this chapter is 19 basically listing it's -- that -- what 20 were some of the, at the time, 21 environmental risk factors for ADHD, 22 none of which haven't shown to be 23 causes, except for the traumatic -- I 24 think I mentioned -- I do mention 25 traumatic brain injury, which as I</p> |

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| <p style="text-align: right;">Page 301</p> <p>1 talk about in my report in the --</p> <p>2 the severe physical and emotional</p> <p>3 deprivation.</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. Take a look at page 8.</p> <p>6 You write that, "Environmental</p> <p>7 risk factor must contribute to the etiology</p> <p>8 of ADHD."</p> <p>9 Is that true?</p> <p>10 A. I -- that's the same as what I</p> <p>11 said before about what we know from twin</p> <p>12 studies. That heritability being 70 --</p> <p>13 roughly 75, 76 percent, there is a role for</p> <p>14 environmental causes.</p> <p>15 That's -- I think almost</p> <p>16 everybody agrees with that.</p> <p>17 Q. Let's go to -- is it fair to</p> <p>18 say that genes and environment combine to</p> <p>19 cause ADHD?</p> <p>20 MS. BROWN: Objection to the</p> <p>21 form.</p> <p>22 THE WITNESS: Again, that is</p> <p>23 the current hypothesis, that genes</p> <p>24 alone, although they have -- that play</p> <p>25 a robust role in the sense of 75,</p> | <p style="text-align: right;">Page 303</p> <p>1 the developing brain."</p> <p>2 Is that true?</p> <p>3 A. Again, the -- what we mean here</p> <p>4 by "implicate" is that these studies have</p> <p>5 generated lots of hypotheses about,</p> <p>6 typically, exposures that could affect the</p> <p>7 developing brain. And they're of much</p> <p>8 interest to people doing research in the area</p> <p>9 because we have known now for quite some time</p> <p>10 that heritability of ADHD is not 100 percent.</p> <p>11 And so we keep -- many of us</p> <p>12 are -- we teach our students, and we teach</p> <p>13 others, that there's an environmental piece,</p> <p>14 and me myself would hope that eventually I</p> <p>15 would understand better the environmental</p> <p>16 causes of ADHD.</p> <p>17 Q. You also write that, "We expect</p> <p>18 that gene-by-environment interaction and</p> <p>19 epigenetic effects mediate these</p> <p>20 environmental risks."</p> <p>21 Is that true?</p> <p>22 A. That -- as stated, that's the</p> <p>23 hypothesis that I would -- I did endorse then</p> <p>24 and I still endorse, that if the environment</p> <p>25 is having an effect, there's a -- there's a</p> |
| <p style="text-align: right;">Page 302</p> <p>1 76 percent of the variants.</p> <p>2 The environment --</p> <p>3 environmental causes, based upon the</p> <p>4 twin data, they must -- they must</p> <p>5 exist. I mean, that's what the --</p> <p>6 that's the -- that's what the twin</p> <p>7 studies say from the point of view of</p> <p>8 genes and environment.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Now, if we -- if someone is</p> <p>11 exposed to multiple environmental risk</p> <p>12 factors, say three, and they acquire ADHD, do</p> <p>13 we conclude that those environmental risk</p> <p>14 factors contributed to causing their ADHD?</p> <p>15 A. Let me just read the question</p> <p>16 again here.</p> <p>17 No. I mean, it depends on,</p> <p>18 well, what those risk factors are, I -- but</p> <p>19 in general -- in general, no.</p> <p>20 Q. Let's take a look at page 11.</p> <p>21 A. Page 11.</p> <p>22 Q. You write here, "Substantial</p> <p>23 data from epidemiological studies implicates</p> <p>24 the environment in the etiology of ADHD.</p> <p>25 These data implicate biological assaults on</p> | <p style="text-align: right;">Page 304</p> <p>1 very good likelihood that some of that is</p> <p>2 gene-environment interaction.</p> <p>3 And some of that -- and that</p> <p>4 means in addition to, it could also be main</p> <p>5 effects of the environment without genes.</p> <p>6 Like traumatic brain injury is a good example</p> <p>7 where it seems to be, if you will, an</p> <p>8 independent effect.</p> <p>9 But I would -- I would expect</p> <p>10 that once this puzzle is solved 50 to</p> <p>11 100 years from now from, we'll -- they'll --</p> <p>12 we'll know about gene-environment</p> <p>13 interactions and that epigenetic effects will</p> <p>14 mediate some of those environmental risks.</p> <p>15 Q. Based on the data you've seen</p> <p>16 to date, your decades of research in ADHD, is</p> <p>17 it your expectation that gene-by-environment</p> <p>18 interactions mediate environmental risks?</p> <p>19 MS. BROWN: Objection to the</p> <p>20 form of the question.</p> <p>21 THE WITNESS: I don't see</p> <p>22 what you say -- let me just look at</p> <p>23 the question. I don't -- the phrasing</p> <p>24 is strange.</p> <p>25</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Well, let me -- let me rephrase</p> <p>3 it then.</p> <p>4 Based on --</p> <p>5 MS. BROWN: He's going to</p> <p>6 withdraw it and ask another question.</p> <p>7 THE WITNESS: Ah, okay. Thank</p> <p>8 you.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Is it your expectation that --</p> <p>11 withdrawn.</p> <p>12 If we've identified an</p> <p>13 environmental risk but we're not certain yet</p> <p>14 about its -- the biological pathway that it</p> <p>15 follows in order to cause AD -- or contribute</p> <p>16 to causing ADHD, is it your expectation that</p> <p>17 it's likely that the environmental risk is</p> <p>18 mediated through genetic or epigenetic</p> <p>19 effects?</p> <p>20 MS. BROWN: I object to the</p> <p>21 form of the question.</p> <p>22 THE WITNESS: It -- it's -- it</p> <p>23 is a very reasonable hypothesis that</p> <p>24 should we discover an environmental</p> <p>25 risk that is actually a cause, that's</p> | <p>1 likely operates?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: It's -- the</p> <p>5 reason I used the word "hypothesis" is</p> <p>6 that the hypothesis is something we</p> <p>7 think is a, you know, reasonable idea</p> <p>8 that I would like people to look into</p> <p>9 because it could be a very productive</p> <p>10 area for research. And there are</p> <p>11 people doing epigenetic and epigenomic</p> <p>12 studies of ADHD, and I think that's</p> <p>13 great.</p> <p>14 But an assumption applies, kind</p> <p>15 of, I assume, that this is true, which</p> <p>16 is not -- it's not the -- it's not</p> <p>17 that part of the scientific method.</p> <p>18 It's a different concept that you</p> <p>19 assume something is true.</p> <p>20 QUESTIONS BY MR. DOVEL:</p> <p>21 Q. If we've identified a risk</p> <p>22 factor for ADHD and determined that it is a</p> <p>23 true risk factor, that is, that it's not</p> <p>24 simply a result of confounding with genes or</p> <p>25 something else, can we then say that</p> |
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| <p>1 one of these exposures that are during</p> <p>2 fetal brain development, that we will</p> <p>3 discover some -- well, when I say</p> <p>4 "we," I'm not -- it's not me. I don't</p> <p>5 do this work, but, you know, the</p> <p>6 field. I mean, when I say "we," I</p> <p>7 mean the field. That the field will</p> <p>8 discover that some of these</p> <p>9 environmental exposures will have --</p> <p>10 will lead to epigenetic changes or</p> <p>11 will create epigenetic marks,</p> <p>12 essentially, is really the best way to</p> <p>13 say that.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Would that be your starting</p> <p>16 assumption?</p> <p>17 MS. BROWN: Objection to the</p> <p>18 form.</p> <p>19 THE WITNESS: Well, I refer to</p> <p>20 this as a hypothesis as opposed to an</p> <p>21 assumption.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. I understand that.</p> <p>24 But would you also -- would</p> <p>25 that be your starting assumption for how it</p> | <p>1 environmental risk factor is a cause of ADHD?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: So, okay. So</p> <p>5 this is a hypothetical risk factor</p> <p>6 where an association has been</p> <p>7 established, and we've ruled out all</p> <p>8 possible confounds. So this</p> <p>9 association -- you know, let's assume</p> <p>10 multiple studies and replications and</p> <p>11 meta-analyses and so forth.</p> <p>12 Geez, that's a good question.</p> <p>13 That, in and of itself, that</p> <p>14 would be -- that kind of data, of</p> <p>15 course, would be much more compelling</p> <p>16 than the data that we're reviewing --</p> <p>17 that I've been reviewing for</p> <p>18 acetaminophen. But of course you'd</p> <p>19 need to go through the Bradford Hill</p> <p>20 criteria to -- before you made --</p> <p>21 before making any kind of causal --</p> <p>22 any statement about whether this is</p> <p>23 causal or not causal.</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. Well, let's back up a second.</p> |

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| <p>1 Let's use as an example 2 smoking, tobacco smoking. Would you accept 3 that tobacco smoking causes lung cancer? 4 A. I don't know the data, but I -- 5 it's something I believe from what I've 6 learned about from various sources. 7 Q. As it turns out, even lifelong 8 smokers, most of them don't get lung cancer, 9 less than 20 percent. So it's a combination 10 of smoking and other factors, perhaps genetic 11 predisposition? 12 A. Uh-huh. 13 Q. Does that sound reasonable? 14 MS. BROWN: I object to the 15 form of the question. 16 THE WITNESS: It sounds 17 reasonable. 18 It's -- I want just to clarify. 19 It's, of course, well outside my area 20 of expertise. I know about as much of 21 this as the average person knows, but 22 it seems -- it's a reasonable 23 statement. 24 QUESTIONS BY MR. DOVEL: 25 Q. Is it -- as you use the term</p> | <p>1 A. That we're -- okay. 2 So it's a hypothetical. It's 3 unconfounded. I'd like to -- I have to look 4 at all the details here because it's a -- 5 MS. BROWN: He can rephrase, if 6 you need. 7 THE WITNESS: Could you 8 rephrase? It's just a complicated 9 question. 10 So it's the hypothetical, 11 unconfounded, statistically 12 significant association across 13 multiple studies, say, in a 14 meta-analysis? 15 QUESTIONS BY MR. DOVEL: 16 Q. Yeah, let's assume that. 17 A. Okay. Got it. Okay. 18 Q. So just to give you the 19 complete question so you've got it. 20 A drug that we've determined 21 through multiple studies has a true 22 association with in utero exposure to fetuses 23 causing -- or resulting in ADHD, can we say 24 then that it is a cause of ADHD? 25 MS. BROWN: I object to the</p> |
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| <p>1 "cause," would you then consider smoking to 2 be a cause of lung cancer? 3 A. Again, that's my understanding 4 from a layperson's perspective of what I've, 5 you know, absorbed over the years. 6 Q. If we have environmental -- an 7 exposure to a drug in utero that we determine 8 has a true association with ADHD, can we then 9 call it a cause; that is, it may not be a 10 sufficient cause all by itself, but it is a 11 cause when combined with other genetic 12 predispositions such that someone would get 13 ADHD? 14 A. So -- 15 MS. BROWN: Objection to the 16 form of the question. 17 THE WITNESS: Okay. 18 So when you say -- I think you 19 used the phrase "true association." 20 And here -- are we talking about -- 21 are we going back to that 22 hypothetical, unconfounded 23 association? 24 QUESTIONS BY MR. DOVEL: 25 Q. Yes.</p> | <p>1 form of the question. 2 THE WITNESS: But isn't this -- 3 I think this is the same question you 4 asked before. And my answer was -- 5 well, I guess the -- did we say -- do 6 we have here what the -- what 7 exactly -- what is the risk ratio for 8 meta-analysis, the assumption about 9 that? 10 QUESTIONS BY MR. DOVEL: 11 Q. Let's assume it's 2. 12 A. It's 2. 13 MS. BROWN: Objection to the 14 form of these questions. 15 THE WITNESS: And so the 16 answer, what I answered before, is 17 that you want to go -- I would want to 18 go through the Bradford Hill criteria 19 for causality before answering that 20 question. 21 QUESTIONS BY MR. DOVEL: 22 Q. Well, let's assume it satisfies 23 temporality. It -- that it satisfies a 24 dose-response relationship. We have 25 consistent data across multiple studies.</p> |

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| <p>1 In that situation, would you 2 agree that you then have something you can 3 call a cause of ADHD? 4 MS. BROWN: I object to the 5 form of the question. 6 THE WITNESS: And there's a 7 plausible biological mechanism that 8 explains the association? 9 QUESTIONS BY MR. DOVEL: 10 Q. Yes. 11 A. What -- in what type of -- this 12 is an exposure, in utero exposure? What kind 13 of exposure are you talking about? 14 Q. In utero exposure, yeah. 15 A. What kind of -- what's -- 16 Q. A drug. 17 MS. BROWN: I object to the 18 form of these questions. 19 THE WITNESS: It's a drug. 20 It would -- it would partly 21 depend upon the nature of the drug. 22 Can you give me any information 23 about the nature of the drug? 24 QUESTIONS BY MR. DOVEL: 25 Q. What nature -- why would the</p> | <p>1 A. Experiments, analogy. We 2 got -- we talked about consistency. Let's 3 see what else we got. 4 So you -- I think what you're 5 saying is that if all the Bradford Hill 6 criteria are met, does it meet Bradford Hill 7 criteria? It's kind of -- it's sort of a 8 circular question, isn't it? 9 Q. Well, it's a question that I 10 posed, and I would like an answer to it 11 without your diagnosing it. 12 MS. BROWN: Well, hold on. 13 You'll give the answer that you think 14 is appropriate, and counsel will 15 follow up. 16 THE WITNESS: Yeah. I'm 17 really -- I'm not trying to be 18 difficult here. It's -- I'm not 19 diagnosing the question. I want to 20 make sure I understand it, that's 21 what -- what's being said here. 22 That we're saying that you 23 have -- you have an association that's 24 totally unconfounded, that 25 everybody -- you know, everybody in</p> |
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| <p>1 nature matter? 2 A. If -- you know, this -- a drug 3 that has known, you know -- I mean, drugs 4 have different effects, right. Some drugs, 5 the effect on the brain is very 6 well-described and very well-known. Other 7 drugs, it's -- it may be unknown. 8 Does the drug -- is there -- is 9 there data suggesting that the drug -- when 10 the mother takes it, it gets into the brain 11 of fetus? What do we know about that, all 12 that? 13 Q. Yeah, let's assume we've got a 14 plausible biological mechanism. It gets to 15 the fetus. The concentrations are sufficient 16 to satisfy the mechanism. We've got a 17 plausible biological mechanism. 18 MS. BROWN: I object to the 19 form of these questions. 20 THE WITNESS: And so are we 21 also assuming that all the other 22 Bradford Hill criteria are met? 23 QUESTIONS BY MR. DOVEL: 24 Q. Well, I think I've covered all 25 of them except analogy.</p> | <p>1 the -- every relevant expert agrees is 2 unconfounded, statistically 3 significant across meta-analyses, 4 there's no publication biases, 5 anything to worry about there. The 6 odds ratio is 2. All Bradford Hill 7 criteria are met. Everybody agrees 8 with that. 9 Then I think Bradford Hill -- 10 you know, it's -- it's still a 11 hypothetical answer because I don't 12 know any of the details, but I think 13 we're saying if the Bradford Hill 14 criteria are met, we have to conclude 15 that the Bradford Hill criteria are 16 met. That -- you know, it is -- in 17 this hypothetical case, causality 18 would be reasonable -- a reasonable 19 direction. 20 QUESTIONS BY MR. DOVEL: 21 Q. In that case the drug, we could 22 say, is a cause of ADHD? 23 MS. BROWN: Objection to the 24 form of that question. 25 THE WITNESS: Well, it</p> |

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| <p>1 certainly wouldn't be, right, the only 2 cause. And whether it's, you know, a 3 necessary cause, sufficient cause, 4 necessary and sufficient cause, I 5 mean, that would be -- it could be 6 a -- well, I mean, we just don't know. 7 I mean, that's -- requires more data. 8 QUESTIONS BY MR. DOVEL: 9 Q. We could say that the drug is a 10 cause of ADHD, right? 11 MS. BROWN: I object to the 12 form of that question. 13 THE WITNESS: Yes, if -- what 14 I'm saying here is that if, as you 15 say, Bradford Hill criteria are 16 satisfied, then we can conclude 17 that this is particular hypothetical 18 drug is a hypothetical cause of ADHD. 19 QUESTIONS BY MR. DOVEL: 20 Q. Before you cite a study, do 21 you -- do you read the study and understand 22 it? 23 A. Yes. 24 Q. Before you rely upon the 25 conclusions in a study, do you check whether</p> | <p>1 the result might not be statistically 2 significant but still interesting because 3 their finding is null. 4 (Faraone Exhibit 705 marked for 5 identification.) 6 QUESTIONS BY MR. DOVEL: 7 Q. Let's take a look at 8 Exhibit 705. 9 This is the Faraone LinkedIn 10 post from August 2016. 11 A. Ah. 12 Q. Now, here you say that "Given 13 that acetaminophen is used in many 14 over-the-counter painkillers, correctly 15 reporting information about acetaminophen and 16 its potential risk to ADHD is crucial." 17 Right? 18 MS. BROWN: Well, objection to 19 the form of that question. 20 THE WITNESS: Which paragraph 21 are you in, sir? 22 QUESTIONS BY MR. DOVEL: 23 Q. First paragraph. 24 A. Oh, yes, I see that. Yes. 25 Q. You write that "Rather than</p> |
| Page 318 | Page 320 |
| <p>1 there are any serious flaws that would make 2 it unreliable? 3 A. I try to do my best, yes. 4 Q. If you cite a study, do you 5 assess whether it has sound methods before 6 you cite it? 7 MS. BROWN: I object to the 8 form of that question. 9 THE WITNESS: That is my goal 10 when I do read studies, yes. 11 QUESTIONS BY MR. DOVEL: 12 Q. Before you cite a study, do you 13 ascertain whether it shows statistically 14 significant results? 15 MS. BROWN: Object to the form. 16 THE WITNESS: Not necessarily. 17 QUESTIONS BY MR. DOVEL: 18 Q. Before you rely upon a study 19 for a conclusion, do you assess whether it's 20 used appropriate controls? 21 A. It depends upon the study, 22 whether a control is essential for the 23 question being asked. The same is true with 24 the statistical significance. I mean, if 25 someone is reporting a negative result, then</p> | <p>1 relying on one study, looking at the big 2 picture using all available studies is best." 3 Is that -- 4 A. That -- that's correct. 5 Q. Is that the correct scientific 6 approach? 7 A. That is correct. 8 Q. And given that we're dealing 9 with acetaminophen in humans, we can't use a 10 randomized trial. We've got to use 11 naturalistic studies, such as epidemiological 12 studies, right? 13 A. Correct. 14 Q. Now, here you cite three 15 studies, and I've looked them up. The first 16 is Liew 2014, the next one is Thomas 2014, 17 and the third one is Avella-Garcia 2016. 18 You read those studies and 19 considered their strengths and weaknesses, 20 right? 21 A. That's correct. 22 Q. For example, Liew 2014, you 23 note that the authors made sure that the 24 results were not accounted for by potential 25 confounds?</p> |

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| <p>1 A. Let me double-check. That 2 might not actually be correct. Or -- well, 3 let me just check that a second. 4 Q. Well, my question is what you 5 wrote here, sir. 6 A. Yeah, I know. I just want 7 to -- there's a nuance with that, I think. 8 But I just want to clarify that with myself. 9 In 2014. 10 That's what's written there, 11 but it was -- in retrospect, I kind of -- 12 looking at that, Liew did something that was 13 kind of unusual in the -- in the old 14 acetaminophen literature, which is that I'm 15 pretty sure this is a study where he does -- 16 he does three separate analyses to address 17 the confounds that I talk about in my table - 18 fever, pain and infection, and perhaps 19 inflammation. 20 I'm giving you some examples 21 here of confounds. This doesn't necessarily 22 mean these are the ones he corrected for, 23 which is -- it's not an ideal way to do -- 24 it's not an ideal way to make the correction. 25 But, yes, I did -- this is what</p> | <p>1 satisfactory? 2 A. It's not an actual -- you see, 3 the thing is it's not actually an adjustment. 4 It's -- 5 Q. All right. He did a 6 stratification to see whether the results 7 could be explained by fever, inflammation -- 8 A. Exactly. He did three -- he 9 did three separate analyses. He did not do 10 an adjustment. 11 Q. And he determined that the 12 results could not be explained by fever, 13 inflammation or infection, right? 14 A. I believe that was his 15 conclusion, yes. 16 Q. And you don't have any dispute 17 with the math that he used in his study, 18 right? 19 A. The only -- the only dispute I 20 have is that it would have been better if he 21 had done -- I'm puzzled why almost everybody 22 else adjusts for these indications in the 23 model, and he doesn't do that. And if he had 24 done that, it would have been much clearer 25 because we would actually get an adjusted</p> |
| Page 322 | Page 324 |
| <p>1 it says. 2 Q. Well, do you agree that Liew 3 2014 accounted for confounding by fever, 4 inflammation and infection? 5 MS. BROWN: Objection to the 6 form. 7 THE WITNESS: They tried to, 8 but I think they didn't do a very good 9 job of it. So the -- in fact -- I'm 10 pretty sure they're -- I labeled them 11 as not adjusting for them. Because 12 they didn't -- it turns out they 13 didn't -- they don't actual do, say -- 14 they don't do a -- they don't do a 15 statistical adjustment in their 16 prediction model -- in their -- in the 17 mathematical model they're using for 18 the analysis. They do separate 19 conditional analyses, which means they 20 never do an analysis where they 21 actually do an adjustment with all of 22 these combined. 23 QUESTIONS BY MR. DOVEL: 24 Q. Dr. Liew did an adjustment, but 25 it's one that you didn't find to be</p> | <p>1 odds ratio from his study. We don't have an 2 adjusted odds ratio or its confidence 3 interval. So he's actually not providing 4 some information that would be very useful in 5 making this evaluation. 6 Q. After reading the Thompson, 7 Liew and Avella-Garcia epidemiological 8 studies in 2016, you believed you could draw 9 few conclusions from the studies, right? 10 A. Not correct. 11 Q. One of the conclusions you 12 believed was accurate was that there does 13 seem to be a weak, yet real association, 14 between maternal use of acetaminophen while 15 pregnant and subsequent ADHD -- 16 A. Uh-huh. 17 Q. -- or ADHD symptoms in the 18 exposed child, right? 19 A. That's correct. 20 Q. And then you wrote this up and 21 published it on LinkedIn? 22 MS. BROWN: Objection to the 23 form. 24 THE WITNESS: That is correct, 25 yes.</p> |

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| <p style="text-align: right;">Page 325</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Okay. I'm now going to turn to</p> <p>3 Exhibit 763.</p> <p>4 A. I just want to -- do want to</p> <p>5 clarify here. We're talking about -- what</p> <p>6 this talks about is that there's weak, yet</p> <p>7 real, meaning statistically significant,</p> <p>8 association.</p> <p>9 I believe that what they're</p> <p>10 reporting is statistically significant, and</p> <p>11 we also make the point here -- I also make</p> <p>12 the point here to say this in this blog</p> <p>13 that -- where do I say that?</p> <p>14 Q. Sir, if you've got some more</p> <p>15 you'd like to say about it, wait until a</p> <p>16 question is asked of me or your counsel.</p> <p>17 This is not your chance just to arbitrarily</p> <p>18 put stuff on the record.</p> <p>19 A. It's not --</p> <p>20 MS. BROWN: Well, he's not --</p> <p>21 he's not --</p> <p>22 THE WITNESS: -- done</p> <p>23 arbitrarily. You're --</p> <p>24 MS. BROWN: Hold on. Hold on.</p> <p>25 MR. DOVEL: No, he wasn't</p> | <p style="text-align: right;">Page 327</p> <p>1 wrote in October of 2017?</p> <p>2 A. I see that, yes.</p> <p>3 Q. Here you refer to a recent CNN</p> <p>4 report, and that's regarding the Ystrom</p> <p>5 study, right?</p> <p>6 A. Ah, yes.</p> <p>7 Q. And then you also cite four</p> <p>8 other studies - Stergiakouli 2016, Thomas --</p> <p>9 Thompson 2014, Liew 2014, and Brandlistuen</p> <p>10 2013.</p> <p>11 Right?</p> <p>12 A. Correct.</p> <p>13 Q. Brandlistuen, that was the</p> <p>14 sibling pair study, right?</p> <p>15 A. Yes. That was the sib --</p> <p>16 sib-control study out of Norway, the first</p> <p>17 one.</p> <p>18 Q. And you comment that, given the</p> <p>19 Ystrom study and these other studies, it</p> <p>20 seems unlikely that the Ystrom study was</p> <p>21 simply a chance finding, right?</p> <p>22 A. That's correct. I said that.</p> <p>23 Q. And then you asked the</p> <p>24 question, "Does it make any biological</p> <p>25 sense?"</p> |
| <p style="text-align: right;">Page 326</p> <p>1 finishing his answer.</p> <p>2 MS. BROWN: He was finishing</p> <p>3 his answer.</p> <p>4 MR. DOVEL: I had moved on, and</p> <p>5 he decided he wanted to clarify</p> <p>6 something.</p> <p>7 MS. BROWN: I think he thought</p> <p>8 he wasn't finished.</p> <p>9 THE WITNESS: I think it's</p> <p>10 important to say that -- it's very</p> <p>11 clear from this, that it's not -- I'm</p> <p>12 not saying -- I'm not saying that</p> <p>13 acetaminophen causes ADHD. It's --</p> <p>14 that's very clear.</p> <p>15 I mean, that's the -- that is</p> <p>16 the goal of these proceedings, is to</p> <p>17 clarify my views on that, and</p> <p>18 that's -- my view is very consistent</p> <p>19 with what I said there.</p> <p>20 (Faraone Exhibit 763 marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. Let's take a look at 763.</p> <p>24 A. Got it.</p> <p>25 Q. This is a LinkedIn post you</p> | <p style="text-align: right;">Page 328</p> <p>1 Right?</p> <p>2 A. Correct.</p> <p>3 Q. Trying to determine whether or</p> <p>4 not there's a plausible biological route by</p> <p>5 which acetaminophen could actually be causing</p> <p>6 this ADHD, right?</p> <p>7 A. I was simply trying to point</p> <p>8 out that -- I think what it says here is that</p> <p>9 it is possible that an environmental exposure</p> <p>10 of this sort could have effects on</p> <p>11 epigenetics.</p> <p>12 I do cite -- I think this is</p> <p>13 Gervin, et al., and this is a study which was</p> <p>14 subsequently not replicated by the same</p> <p>15 group. So that turned out not to be correct.</p> <p>16 But it did -- it caught my</p> <p>17 interest that someone had actually done a</p> <p>18 study looking at the epigenetics.</p> <p>19 Q. When you asked "does it make</p> <p>20 any biological sense," you're asking whether</p> <p>21 this is something that would be impossible</p> <p>22 biologically or whether there's a plausible</p> <p>23 biological route, right?</p> <p>24 MS. BROWN: Objection to the</p> <p>25 form.</p> |

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| <p>1 THE WITNESS: I guess I'd 2 restate that as I'm trying to -- 3 remember that, you -- of course, a 4 blog is a -- it's an informal post 5 that is meant to engage people with 6 the evidence. It's one of the -- my 7 goals in this current phase of my 8 career. 9 It's not meant to be an 10 in-depth -- it's typically, what, 11 500 words. It's not meant to be an 12 in-depth dive into any specifics -- 13 any specific issue or paper. It's 14 just meant to tell people, these are 15 papers that are worth reading. 16 And I'm someone who felt that 17 this -- these particular papers were 18 worth reading, and I drew the 19 attention to the epigenetic study 20 because it is -- again, it is the hope 21 of many of us in the field that one 22 day we'll understand how environmental 23 exposures are involved in causing 24 ADHD, and I thought this is a good 25 direction.</p> | <p>1 MS. BROWN: Go ahead. 2 THE WITNESS: That -- you've 3 read it -- you have read it correctly, 4 yes. 5 QUESTIONS BY MR. DOVEL: 6 Q. Now, go back to the, but "Does 7 it make any biological sense." 8 You're posing a question there, 9 right? 10 A. Correct. 11 Q. And you answered the question? 12 A. Excuse me? 13 Q. You answered the question? 14 You posed the question, "Does 15 it make any biological sense," and then you 16 provide an answer to that question? 17 A. Yes. That's what I just 18 discussed about the epigenetic study there. 19 Q. And you concluded it did make 20 biological sense, that acetaminophen exposure 21 during pregnancy could cause ADHD? 22 MS. BROWN: I object to the 23 form of the question. 24 THE WITNESS: Yeah, the 25 conclusion here says, based -- start</p> |
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| <p>1 I was glad -- I was really 2 happy to see somebody doing it. I 3 think that's great. It's too bad that 4 later on it wasn't -- you know, it 5 wasn't replicated, but it wasn't 6 replicated. That's life. 7 QUESTIONS BY MR. DOVEL: 8 Q. Now -- 9 A. And again, just because we're 10 talking about causality, the -- this blog is 11 very clear that we can't assert there's a 12 causal link. 13 Q. Well, it doesn't actually say 14 that. It says "We can't assert with 15 certainty that there's a causal link." 16 Right? 17 A. That's what it says, exactly. 18 Q. Yeah. It doesn't say "we 19 cannot assert that there is likely a causal 20 link." It says "We cannot assert with 21 certainty," right? 22 A. Well -- 23 MS. BROWN: Objection to the 24 form of the question. 25 THE WITNESS: Yep.</p> | <p>1 with that question is acetaminophen -- 2 we have a study that shows that it 3 is -- it is making epigenetic changes, 4 which is extremely interesting. 5 It's no longer interesting 6 because it wasn't replicated, but it 7 was at the time interesting, and so 8 I'm -- that's why I'm drawing people's 9 attention to it in this -- in this 10 blog. 11 And then, you know, again, 12 it's -- I don't -- I'm not concluding 13 that it's -- it's causal, and I'm also 14 pointing out that there could be an 15 unmeasured third factor that's 16 accounting for these results. 17 QUESTIONS BY MR. DOVEL: 18 Q. The researchers, Ystrom and 19 Liew and others, in your view, they did a 20 respectable job of ruling out third factors, 21 right? 22 MS. BROWN: Objection to the 23 form. 24 THE WITNESS: Yeah. 25 Respectable I -- is a word that -- I</p> |

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| <p>1 think I would say I chose that because</p> <p>2 it's sort of the way of saying that</p> <p>3 they did is -- it looks like they may</p> <p>4 have done -- it doesn't mean that they</p> <p>5 did everything -- everything possible.</p> <p>6 It doesn't mean they did the</p> <p>7 ideal study because in -- given that</p> <p>8 it's an epidemiologic study, it -- we</p> <p>9 call these studies of convenience.</p> <p>10 They're not studies that are -- that</p> <p>11 are designed explicitly to study</p> <p>12 acetaminophen and ADHD. They're</p> <p>13 studies that typically are using</p> <p>14 databases that have been generated</p> <p>15 for other purposes.</p> <p>16 And so given the constraints</p> <p>17 they have, they did a respectable job,</p> <p>18 but they don't -- they're not -- they</p> <p>19 don't -- they don't address all</p> <p>20 confounds, which is why I talk about</p> <p>21 the confounding is a potentially --</p> <p>22 potentially a problem, which is why I</p> <p>23 can't assert causality.</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. And then at the conclusion of</p> | <p>1 MS. BROWN: Objection to the</p> <p>2 form.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. You say, bring this information</p> <p>5 to your physician and ask if there's a</p> <p>6 suitable alternative?</p> <p>7 A. Yeah, because I'm saying here,</p> <p>8 we've got an article about acetaminophen.</p> <p>9 That's one painkiller. There are other</p> <p>10 painkillers.</p> <p>11 I -- I'm not an expert on what</p> <p>12 doctors do about painkillers during</p> <p>13 pregnancy, so I'm just saying, if you're</p> <p>14 concerned about this, ask your doctor about</p> <p>15 what -- I mean, it's what I do when I go to</p> <p>16 my doctor. I got -- you know, he's going</p> <p>17 to -- I got this problem, I say, what are my</p> <p>18 alternatives for it.</p> <p>19 So I'm just saying, talk to</p> <p>20 your doctor, find out what your doctor</p> <p>21 suggests.</p> <p>22 I'm not --</p> <p>23 Q. The reason --</p> <p>24 A. I'm not a physician, so I'm not</p> <p>25 going to be giving -- telling them what they</p> |
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| <p>1 your writings on the Ystrom and other</p> <p>2 studies, you offer some advice to pregnant</p> <p>3 women, right?</p> <p>4 A. Yeah, basic --</p> <p>5 MS. BROWN: Object. Objection</p> <p>6 to the form.</p> <p>7 Go ahead.</p> <p>8 THE WITNESS: Well, basically</p> <p>9 say if -- you know, basically that's</p> <p>10 what I'm saying is -- excuse me.</p> <p>11 I think my thinking here was</p> <p>12 that if someone is reading this and</p> <p>13 they're pregnant and if they for some</p> <p>14 reason get worried, I'm saying, just</p> <p>15 talk to your doctor about this.</p> <p>16 I don't want them to think I'm</p> <p>17 giving them any -- I'm giving them any</p> <p>18 advice. Talk to your doctor about</p> <p>19 this.</p> <p>20 QUESTIONS BY MR. DOVEL:</p> <p>21 Q. Well, aren't you minimizing</p> <p>22 your actual words? You don't just say, talk</p> <p>23 to you doctor about this, do you?</p> <p>24 Is that what you tell them,</p> <p>25 talk to your doctor about this?</p> | <p>1 should do or shouldn't do, and I don't</p> <p>2 want -- I don't want the blog misinterpreted</p> <p>3 as a direction to -- I don't want the blog</p> <p>4 misinterpreted as a direction that, oh, you</p> <p>5 shouldn't take acetaminophen. I want them</p> <p>6 to -- if they're concerned about it, to talk</p> <p>7 to their doctor.</p> <p>8 Q. Are you asking -- withdrawn.</p> <p>9 Do you suggest that they ask if</p> <p>10 there's an alternative because these</p> <p>11 epigenetic studies demonstrated a risk?</p> <p>12 MS. BROWN: I object to the</p> <p>13 form of that question.</p> <p>14 THE WITNESS: The blog ends as</p> <p>15 it does, because that -- nothing</p> <p>16 specific about the epigenetic study.</p> <p>17 It's -- the blog ends as it does</p> <p>18 because I'm thinking to myself, maybe</p> <p>19 some pregnant woman is reading about</p> <p>20 this, and even though we can't say</p> <p>21 this is causal, if they're worried</p> <p>22 about it, they should know that they</p> <p>23 should talk to their doctor.</p> <p>24 They shouldn't take this as any</p> <p>25 kind of instruction from me that they</p> |

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| <p>1 shouldn't take acetaminophen. They</p> <p>2 should talk to their doctor about</p> <p>3 that.</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. Now, doctors, they're the ones</p> <p>6 that are responsible for balancing the</p> <p>7 benefits and risks of various medication and</p> <p>8 advising their patients, right?</p> <p>9 A. Absolutely, yes.</p> <p>10 Q. For doctors to do that</p> <p>11 balancing, they've got to be aware of the</p> <p>12 risks, right?</p> <p>13 MS. BROWN: I object to form.</p> <p>14 THE WITNESS: I honestly don't</p> <p>15 know how they do that, but they need</p> <p>16 to be -- you know, they have these</p> <p>17 regulators tell them things to do.</p> <p>18 It's -- they have labels on the drugs</p> <p>19 that tell them what to do.</p> <p>20 There's a -- I know a little</p> <p>21 bit about that world, but it's not</p> <p>22 anywhere -- it's outside of my</p> <p>23 expertise.</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. Do you know this much, that for</p> | <p>1 improve their abilities -- the abilities that</p> <p>2 they could deal with ADHD in their countries.</p> <p>3 One of the reasons we created</p> <p>4 the World Federation Guide was to communicate</p> <p>5 to broadly -- I mean, one of the reasons we</p> <p>6 made it -- it's free, obviously, so we made</p> <p>7 it for free so that particularly people in</p> <p>8 limited countries -- those low and middle</p> <p>9 income countries, would have access to</p> <p>10 information when -- sometimes it's difficult</p> <p>11 to get access to because they can't afford --</p> <p>12 literally can't afford to buy the books and</p> <p>13 so forth or get access to the journal</p> <p>14 articles.</p> <p>15 So we're -- we're involved in</p> <p>16 those kinds of outreach activities as well.</p> <p>17 Q. One of the missions of the</p> <p>18 World Federation of ADHD is to provide</p> <p>19 accurate information about ADHD, right?</p> <p>20 A. I don't know if it's in our</p> <p>21 mission statement, but the -- certainly we</p> <p>22 run -- each of those activities that we run,</p> <p>23 we -- that's our goal, is to provide accurate</p> <p>24 information.</p> <p>25 Q. And to eliminate</p> |
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| <p>1 them to balance risks, they have to be aware</p> <p>2 of the risks?</p> <p>3 MS. BROWN: I object to the</p> <p>4 form.</p> <p>5 THE WITNESS: And to balance</p> <p>6 risks. If they -- if they're going to</p> <p>7 take something into consideration,</p> <p>8 they need to know about that</p> <p>9 something.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. Has the World Federation of</p> <p>12 ADHD and its members undertaken research to</p> <p>13 determine the causes of ADHD?</p> <p>14 A. Well, let me clarify. The</p> <p>15 World Federation is not a -- it's not an</p> <p>16 academic institution. It's not a research</p> <p>17 organization. It is primarily -- its main</p> <p>18 function is to host a meeting amongst</p> <p>19 researchers and clinicians from around the</p> <p>20 world to educate them about what's happening</p> <p>21 in ADHD. That's its main goal.</p> <p>22 Its second goal is to perform</p> <p>23 outreach in many different -- in different</p> <p>24 ways to -- for example, we had some outreach</p> <p>25 to some third world countries trying to</p> | <p>1 misinformation?</p> <p>2 A. And to eliminate</p> <p>3 misinformation, which is unfortunately a big</p> <p>4 problem in this area.</p> <p>5 Q. And the World Federation of</p> <p>6 ADHD Guide, in part it was aimed at</p> <p>7 professionals, doctors and people who are</p> <p>8 treating ADHD, right?</p> <p>9 A. That's fair.</p> <p>10 Q. The International Consensus</p> <p>11 Statement, it was also aimed at</p> <p>12 professionals, right?</p> <p>13 A. That's a good question. It</p> <p>14 was -- it was conceived as a document where</p> <p>15 we're trying to tabulate, according to some</p> <p>16 very specific guidelines, what we felt were</p> <p>17 the most well-defended findings in a sense</p> <p>18 that we didn't think they would -- we didn't</p> <p>19 they would be overturned in the near future,</p> <p>20 let's say, that they were very solid</p> <p>21 findings.</p> <p>22 It wasn't meant to be -- it's</p> <p>23 not meant to be everything about ADHD, but</p> <p>24 it had the limited kind of mandate that we</p> <p>25 describe in the introduction and methods</p> |

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| <p>1 section.</p> <p>2 And, yes, we expected that</p> <p>3 professionals would certainly read it.</p> <p>4 Surgeons would read it, and we're hoping also</p> <p>5 that particularly parents will read it and,</p> <p>6 in fact, I have it posted. It's an open</p> <p>7 access article, so I would post it on my</p> <p>8 website so that parents can read it as well</p> <p>9 or people -- or adults with ADHD can read it.</p> <p>10 Q. Would you expect that the</p> <p>11 participants in that International Consensus</p> <p>12 Statement, members of the World Federation of</p> <p>13 ADHD, would have more information, more</p> <p>14 updated information about the causes of ADHD</p> <p>15 than the typical OB/GYN that's treating their</p> <p>16 patients?</p> <p>17 MS. BROWN: I object to the</p> <p>18 form of the question.</p> <p>19 THE WITNESS: That would be my</p> <p>20 expectation, yes.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Would you expect that the World</p> <p>23 Federation of ADHD would have more</p> <p>24 information about the causes of ADHD and risk</p> <p>25 factors for ADHD than ACOG, the organization</p> | <p>1 people, 80-plus people.</p> <p>2 Those are -- those are the</p> <p>3 people responsible for it, not the -- it's</p> <p>4 not the World Federation writing it.</p> <p>5 (Faraone Exhibit 764 marked for</p> <p>6 identification.)</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. Let's take a look at</p> <p>9 Exhibit 764.</p> <p>10 MS. BROWN: And, Counsel, when</p> <p>11 we're done with this next exhibit, can</p> <p>12 we take a break?</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. This is the Faraone APSARD</p> <p>15 blog.</p> <p>16 This is a blog post that you</p> <p>17 wrote that appeared on the website of the</p> <p>18 American Professional Society of ADHD and</p> <p>19 Related Disorders, APSARD.</p> <p>20 Is that right?</p> <p>21 A. That is correct, yes.</p> <p>22 Q. Now, this appears to be a</p> <p>23 reprint of your August 2016 LinkedIn post.</p> <p>24 A. That's correct, yes.</p> <p>25 Q. And here you published it again</p> |
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| <p>1 that governs OB/GYNs?</p> <p>2 MS. BROWN: I object to the</p> <p>3 form of this question.</p> <p>4 THE WITNESS: Well, let me back</p> <p>5 up a second because I just realized</p> <p>6 you're saying the World Federation of</p> <p>7 ADHD. So it's not -- it's -- the</p> <p>8 consensus statement was written by a</p> <p>9 group of authors, right?</p> <p>10 That's -- if you -- if by the</p> <p>11 World Federation you mean those</p> <p>12 authors who wrote the consensus</p> <p>13 statement, yes, those authors have</p> <p>14 more information.</p> <p>15 The World Federation is not</p> <p>16 a -- you know, doesn't have</p> <p>17 information. It's just a -- it's a --</p> <p>18 it's a professional body of -- that</p> <p>19 runs -- that essentially runs meetings</p> <p>20 and disseminates information.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. It disseminated the</p> <p>23 International Consensus Statement, right?</p> <p>24 A. Correct. But that was written</p> <p>25 by a group of what -- I forget how many</p> | <p>1 on May 18, 2020.</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: Ah, that's</p> <p>5 correct, yes.</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. On APSARD?</p> <p>8 A. That's correct.</p> <p>9 MR. DOVEL: Let's go ahead and</p> <p>10 take a break.</p> <p>11 MS. BROWN: Thanks.</p> <p>12 VIDEOGRAPHER: The time right</p> <p>13 now is 3:01 p.m. We are off the</p> <p>14 record.</p> <p>15 (Off the record at 3:01 p.m.)</p> <p>16 VIDEOGRAPHER: The time right</p> <p>17 now is 3:17 p.m. We're back on the</p> <p>18 record.</p> <p>19 (Faraone Exhibit 765 marked for</p> <p>20 identification.)</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. I'm going to mark as</p> <p>23 Exhibit 765 the Faraone blog post from</p> <p>24 March 14, 2021.</p> <p>25 Is this your blog post that you</p> |

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| <p style="text-align: right;">Page 345</p> <p>1 posted on the ADHD Evidence Project?</p> <p>2 A. Yes, it is.</p> <p>3 Q. Do you run the ADHD Evidence</p> <p>4 Project?</p> <p>5 A. Yes.</p> <p>6 Q. Is the -- one of the goals of</p> <p>7 the ADHD Evidence Project to provide sound</p> <p>8 scientific evidence of the causes of ADHD?</p> <p>9 MS. BROWN: Objection to the</p> <p>10 form.</p> <p>11 THE WITNESS: Yeah. The goal</p> <p>12 of it is to communicate evidence about</p> <p>13 ADHD in all areas.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. Including causation?</p> <p>16 A. Including etiology, yes,</p> <p>17 everything.</p> <p>18 Q. Causation?</p> <p>19 A. Including causation, yeah.</p> <p>20 Q. Now, in this blog post you</p> <p>21 essentially repeated that earlier post you</p> <p>22 had discussing three acetaminophen</p> <p>23 epidemiology studies with ADHD, right?</p> <p>24 A. Correct.</p> <p>25 (Faraone Exhibit 766 marked for</p> | <p style="text-align: right;">Page 347</p> <p>1 blogs posted on this website. Kind of --</p> <p>2 basically trying to move them from finding a</p> <p>3 home from them here.</p> <p>4 Q. You believed as of March 16,</p> <p>5 2021, that it provided -- this blog post</p> <p>6 provided reliable evidence about the</p> <p>7 relationship between ADHD and acetaminophen?</p> <p>8 A. I would say that the blog</p> <p>9 itself reflects what I was thinking back when</p> <p>10 it was written, and I simply moved my</p> <p>11 blogs -- I wanted my blogs to be housed in</p> <p>12 one place and --</p> <p>13 Q. Well, this wasn't a blog --</p> <p>14 MS. BROWN: No, I don't think</p> <p>15 he was done. Let's let him finish,</p> <p>16 please.</p> <p>17 THE WITNESS: Yeah.</p> <p>18 So the Evidence Project -- when</p> <p>19 I created the ADHD Evidence Project,</p> <p>20 one of the reasons was I wanted a</p> <p>21 place -- I had written blogs and some</p> <p>22 of them ended up in LinkedIn, some of</p> <p>23 them sometimes ended up in APSARD. I</p> <p>24 wanted a place that was, if you will,</p> <p>25 my website where I could house my</p> |
| <p style="text-align: right;">Page 346</p> <p>1 identification.)</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Let's take a look at the</p> <p>4 Exhibit 766, which would be the March 16,</p> <p>5 2021, Faraone blog post.</p> <p>6 This is another blog post from</p> <p>7 the ADHD Evidence Project, right?</p> <p>8 A. Yeah. Okay.</p> <p>9 Okay. Yeah, this is the same</p> <p>10 one. Yeah.</p> <p>11 Q. And this is the one that's a</p> <p>12 repeat of the one involving Ystrom, right?</p> <p>13 A. That is correct.</p> <p>14 Q. And you wrote this?</p> <p>15 A. Yes, it's the same one.</p> <p>16 Q. And you were the one that</p> <p>17 posted it?</p> <p>18 A. Yes. Well, it was posted by --</p> <p>19 I have social media people that put stuff up</p> <p>20 on the web. I don't actually put it up on</p> <p>21 the web myself, but I had -- I had it posted</p> <p>22 yes.</p> <p>23 Q. You directed someone to post</p> <p>24 it?</p> <p>25 A. Yeah, I basically had all of my</p> | <p style="text-align: right;">Page 348</p> <p>1 blogs.</p> <p>2 So I moved all of them into</p> <p>3 this -- I'm pointed to this, but it's</p> <p>4 into the web -- into the ADHD Evidence</p> <p>5 Project website.</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. Well, it wasn't the case where</p> <p>8 you just simply one day took them all from</p> <p>9 one place and moved them over to another.</p> <p>10 You, over time, decided which</p> <p>11 ones you wanted to post when, right?</p> <p>12 A. I basically just essentially</p> <p>13 had them posted at intervals. I didn't -- I</p> <p>14 didn't specifically decide, I want this one</p> <p>15 posted in March 16, 2021.</p> <p>16 Q. Let's go back to Exhibit 771.</p> <p>17 That's the excerpts from your slide</p> <p>18 presentation, the overview of</p> <p>19 attention-deficit/hyperactivity disorder.</p> <p>20 A. Yep. Got it.</p> <p>21 Q. You created this slide deck so</p> <p>22 that people could use it to provide</p> <p>23 presentations about various subjects related</p> <p>24 to ADHD, right?</p> <p>25 A. That is correct. Part of --</p> |

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|---|--|
| <p>1 yeah, one of my goals. Yes.</p> <p>2 Q. If you turn to the second page</p> <p>3 of this document, Causes of ADHD, this is</p> <p>4 actually -- if you were at the original slide</p> <p>5 deck, it would be Slide 21.</p> <p>6 So included in your</p> <p>7 presentation that's on the ADHD Evidence</p> <p>8 Project is this slide deck about the causes</p> <p>9 of ADHD, right?</p> <p>10 A. I'd have to see the whole slide</p> <p>11 deck. You're saying is the -- is your</p> <p>12 question, is the slide deck just about the</p> <p>13 causes of ADHD?</p> <p>14 Q. No.</p> <p>15 A. No. What's the question?</p> <p>16 Q. The slide deck covers a number</p> <p>17 different topics, right?</p> <p>18 A. Okay. Yes.</p> <p>19 Q. One of them is the causes of</p> <p>20 ADHD?</p> <p>21 A. This is correct, yes.</p> <p>22 Q. And that appears on your ADHD</p> <p>23 Evidence --</p> <p>24 A. That does, correct. Yes. Yes.</p> <p>25 Q. In fact, the bottom of it says,</p> | <p>1 hypothesis -- we're talking about a</p> <p>2 hypothesis, right. The hypothesis is</p> <p>3 that there's --</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. Okay.</p> <p>6 A. -- genomic causes. We know</p> <p>7 some of them. We think we -- you know, we're</p> <p>8 getting a good handle on that. And I believe</p> <p>9 that there are also environmental causes. We</p> <p>10 just don't know them yet. That's the</p> <p>11 position that I take.</p> <p>12 So here, I'm listing</p> <p>13 potential -- well, remember -- we have to</p> <p>14 also remember for people reading this that</p> <p>15 this is a slide deck, which means that</p> <p>16 it's just -- it's used to -- what's the word</p> <p>17 for it? Prompt me to talk to an audience.</p> <p>18 Q. Sir, the leading -- withdrawn.</p> <p>19 This is not just to prompt you.</p> <p>20 This is something that you put up on --</p> <p>21 A. Well, it's to prompt anyone,</p> <p>22 yes, who is using it.</p> <p>23 Q. And as we discussed, the</p> <p>24 leading hypothesis about the cause of ADHD is</p> <p>25 that it is a combination of environmental</p> |
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| <p>1 "Slide courtesy of http://www.adhdevidence.org."</p> <p>2 Right?</p> <p>3 A. Correct. Yes.</p> <p>4 Q. And the very next slide after</p> <p>5 Causes of ADHD is this one called,</p> <p>6 "Modifiable environmental risk factors for</p> <p>7 ADHD."</p> <p>8 A. I recognize it, yes.</p> <p>9 Q. So this is a slide that's in</p> <p>10 your causes of ADHD section of your slides</p> <p>11 that appear on your ADHD Evidence Project,</p> <p>12 right?</p> <p>13 A. That's correct.</p> <p>14 And I do want to make a point</p> <p>15 here that because the phrase "risk factors"</p> <p>16 is sometimes misinterpreted by lay people.</p> <p>17 Risk factor is the same as correlate. It's</p> <p>18 not -- it's not the same as cause.</p> <p>19 Q. Well, as we talked about, we</p> <p>20 know that ADHD is caused by a combination of</p> <p>21 genetic and environmental risk factors,</p> <p>22 right?</p> <p>23 MS. BROWN: Objection to the</p> <p>24 form.</p> <p>25 THE WITNESS: Well, the</p> | <p>1 risk factors and genetic risk factors, right?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form.</p> <p>4 THE WITNESS: Yes, that's --</p> <p>5 I'm on record as saying that these</p> <p>6 risks -- that there are both -- both</p> <p>7 types of risks are -- exist that we</p> <p>8 need to discover, yes.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. And here you identify some of</p> <p>11 those environmental risk factors for ADHD?</p> <p>12 A. Correct.</p> <p>13 Q. One of them is acetaminophen --</p> <p>14 acetaminophen exposure to the fetus, right?</p> <p>15 A. Yes, that's in here.</p> <p>16 Q. That would be if a pregnant</p> <p>17 woman were to take acetaminophen, the fetus</p> <p>18 would be exposed to it; you've identified</p> <p>19 that as an environmental risk factor for</p> <p>20 ADHD?</p> <p>21 A. It's -- it is one of -- at the</p> <p>22 time the slide was done, it's one of the</p> <p>23 correlates that have -- that have been shown</p> <p>24 to be statistically significant across</p> <p>25 multiple studies.</p> |

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| <p>1 Q. My question was, you identified 2 it as an environmental risk factor for ADHD? 3 MS. BROWN: Objection to the 4 form. 5 THE WITNESS: I understand what 6 you're saying, but I'm trying to be 7 very clear because sometimes the word 8 "risk" is misinterpreted. And risk 9 is -- risk factor just means that it's 10 a correlate. It doesn't mean it 11 causes it. 12 QUESTIONS BY MR. DOVEL: 13 Q. Did you identify 14 acetaminophen exposure to the fetus as a 15 environmental risk factor for ADHD in this 16 slide? 17 MS. BROWN: Objection to the 18 form. 19 THE WITNESS: What the slide 20 identifies, that is acetaminophen is 21 one of several correlates that have 22 been found to be associated with ADHD. 23 QUESTIONS BY MR. DOVEL: 24 Q. No, sir, you're minimizing. 25 Does the word "correlate"</p> | <p>1 Q. The consensus -- 2 MS. BROWN: Wait. Please let 3 him finish. 4 QUESTIONS BY MR. DOVEL: 5 Q. I'm sorry. Were you done? 6 A. What I would say is that in my 7 experience, certainly in the circles in which 8 I travel, the phrase "risk factor" is used 9 synonymously with "correlate." In fact, in 10 the consensus statement, we use those -- we 11 use those synonymously. 12 Q. Is it the consensus in the ADHD 13 field that the term "risk factor for ADHD" 14 means the same thing as "correlate for ADHD"? 15 A. Yes. 16 Q. If we've identified a consensus 17 correlate for ADHD, that's the same as saying 18 we've identified a consensus risk factor for 19 ADHD? 20 MS. BROWN: Objection to the 21 form. 22 THE WITNESS: Yes. Yes. 23 That's what I was trying to say. 24 Thank you. 25</p> |
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| <p>1 appear on this slide? 2 A. I'm -- 3 MS. BROWN: Hold on. 4 THE WITNESS: Well, this is why 5 I'm doing this. Because I'm not 6 minimizing. 7 The phrase "risk factors" is 8 identical to the phrase -- to the word 9 "correlate." 10 QUESTIONS BY MR. DOVEL: 11 Q. Does the word "correlate" 12 appear on this slide? 13 A. The word "correlate" doesn't 14 appear on the slide. It's like any synonym. 15 Sometimes you use one phrase, sometimes you 16 use another. So -- 17 Q. Risk factor and correlate are 18 synonyms in your mind? 19 A. Risk factors and correlates are 20 synonyms. It's how they're used in the 21 field. It's not just in my mind. I'm not 22 inventing this. You can -- you can -- you'll 23 find many other people -- I'm not the only 24 person that has that -- that views them as 25 synonymous. And --</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. Would you agree, sir, that 3 acetaminophen -- withdrawn. 4 Would you agree, sir, that it's 5 the scientific consensus that acetaminophen 6 is a risk factor for ADHD? 7 MS. BROWN: Objection to the 8 form. 9 THE WITNESS: I'm going to 10 answer it the same way I answered it 11 before because you've asked me this 12 question already. 13 That understanding that what I 14 mean by risk factor is correlate, yes, 15 acetaminophen is a correlate of -- I'm 16 sorry, exposure -- maternal use of -- 17 maternal use of acetaminophen during 18 pregnancy is a correlate of ADHD. 19 QUESTIONS BY MR. DOVEL: 20 Q. Is it the scientific consensus 21 that exposure to acetaminophen during 22 pregnancy is a risk factor for ADHD? 23 MS. BROWN: Objection to the 24 form of the same question. 25 THE WITNESS: I would say it's</p> |

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| <p>1 a consensus in the sense that our</p> <p>2 consensus statement, published in</p> <p>3 2021, includes acetaminophen as one of</p> <p>4 the environmental correlates of ADHD.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. That consensus -- it was</p> <p>7 published, as you said, right?</p> <p>8 A. Yes. That's published in the</p> <p>9 peer-reviewed scientific journal,</p> <p>10 Neuroscience & Biobehavioral Reviews.</p> <p>11 Q. And as of today, has that</p> <p>12 publication been retracted?</p> <p>13 A. No.</p> <p>14 Q. Has the statement regarding the</p> <p>15 relationship between acetaminophen and ADHD</p> <p>16 been retracted or withdrawn?</p> <p>17 A. I'm sorry, what statement are</p> <p>18 we referring to?</p> <p>19 Q. The statement that</p> <p>20 acetaminophen has an association -- exposure</p> <p>21 to acetaminophen has an exposure --</p> <p>22 withdrawn.</p> <p>23 There's a -- you're familiar</p> <p>24 with there's a Statement 38 that appears in</p> <p>25 the consensus statement?</p> | <p>1 greater likelihood of ADHD in children?</p> <p>2 A. So to clarify, it's not the</p> <p>3 scientific consensus. It's -- this is just</p> <p>4 the consensus of the people who -- authors of</p> <p>5 the articles who are, you know, all people</p> <p>6 that I respect.</p> <p>7 Q. Well, would you agree that the</p> <p>8 people -- that this -- by including these 77</p> <p>9 people, including yourself, the late Joseph</p> <p>10 Biederman, others, that this would represent</p> <p>11 fairly the scientific consensus on the causes</p> <p>12 of ADHD?</p> <p>13 MS. BROWN: I object to the</p> <p>14 form of that question.</p> <p>15 THE WITNESS: Well, I -- I'm</p> <p>16 having a hard time with "scientific</p> <p>17 consensus" because it's -- the work</p> <p>18 here is the -- and the consensus is</p> <p>19 the consensus of the individuals in</p> <p>20 this -- I'm not saying that there</p> <p>21 are -- well, maybe other scientists</p> <p>22 who disagree with some items. There's</p> <p>23 a lot of items that, as you know, 208</p> <p>24 items, so it's -- I can't say that all</p> <p>25 science agrees with them. But 200 --</p> |
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| <p>1 A. Could we -- could we -- I don't</p> <p>2 have a copy with me. Do you have a copy?</p> <p>3 Q. Yes. Let's do that.</p> <p>4 A. Yeah, let's look at that.</p> <p>5 (Faraone Exhibit 781 marked for</p> <p>6 identification.)</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. I'm going to mark as</p> <p>9 Exhibit 781 the consensus statement.</p> <p>10 So we're going to look at a</p> <p>11 number of parts of this. Let's turn to</p> <p>12 statement 38.</p> <p>13 A. Yep.</p> <p>14 Q. Statement 38 represents one of</p> <p>15 the evidence-based conclusions that the</p> <p>16 scientific community has concluded regarding</p> <p>17 the causes of ADHD, right?</p> <p>18 MS. BROWN: Objection to the</p> <p>19 form.</p> <p>20 THE WITNESS: Yes, that's</p> <p>21 correct. Yes. Yes.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. And the scientific consensus is</p> <p>24 that maternal use of acetaminophen during</p> <p>25 pregnancy was associated with a 33 percent</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. I'm not saying all science, but</p> <p>3 a consensus view.</p> <p>4 MS. BROWN: Let him finish.</p> <p>5 Please. Please, sir.</p> <p>6 THE WITNESS: Isn't that what a</p> <p>7 consensus means? A consensus means</p> <p>8 everybody agrees.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Okay. Would you agree, sir,</p> <p>11 that this Exhibit 781 represents the</p> <p>12 consensus view of the World Federation of</p> <p>13 ADHD?</p> <p>14 A. I wouldn't say that. I would</p> <p>15 say that it's the consensus view of the</p> <p>16 people who wrote -- who are the authors on</p> <p>17 the article.</p> <p>18 Q. Please read the title of it for</p> <p>19 us.</p> <p>20 A. Yes. It's titled, "The World</p> <p>21 Federation of ADHD International Consensus</p> <p>22 Statement, 208 evidence-based conclusions</p> <p>23 about the disorder."</p> <p>24 Q. It was authored by 77 highly</p> <p>25 respected folks in the field of ADHD, right?</p> |

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| <p>1 A. That's correct, yes.</p> <p>2 Q. And the consensus -- withdrawn.</p> <p>3 Would you agree that this</p> <p>4 collection represented the bulk of the</p> <p>5 leading ADHD researchers in the world?</p> <p>6 A. I couldn't say off the top of</p> <p>7 my head if it's the bulk. There are lots --</p> <p>8 there are other ADHD researchers, but it's a</p> <p>9 nice sampling of people from around the</p> <p>10 world.</p> <p>11 Q. These aren't just a sampling of</p> <p>12 people. These are selected, hand-picked by</p> <p>13 you, to be the leading researchers in the</p> <p>14 field, right?</p> <p>15 A. They're not all leading</p> <p>16 researchers. Some of them are leading</p> <p>17 clinicians in their -- in their regions, not</p> <p>18 necessarily -- I wouldn't consider them to be</p> <p>19 leading researchers.</p> <p>20 Q. Leading researchers and</p> <p>21 clinicians in their region.</p> <p>22 A. Correct. Right.</p> <p>23 Q. In addition to the authors,</p> <p>24 another more than 300 people signed on to</p> <p>25 this --</p> | <p>1 consensus.</p> <p>2 The consensus -- that's not --</p> <p>3 the way you phrased it is not</p> <p>4 accurate. The consensus is that --</p> <p>5 well, if you will, that each of the</p> <p>6 items in here were -- met the criteria</p> <p>7 that we set out as being, if you will,</p> <p>8 evidence-based statements about ADHD</p> <p>9 that one way I describe it as unlikely</p> <p>10 to be -- evidence-based findings that</p> <p>11 are unlikely to be overturned in the</p> <p>12 near future.</p> <p>13 But it's a little bit different</p> <p>14 than saying everybody thinks that</p> <p>15 there's a 33 percent increase because</p> <p>16 there's more than one acetaminophen</p> <p>17 study.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Was one of the evidence-based</p> <p>20 findings that is unlikely to be overturned</p> <p>21 that acetaminophen during pregnancy is</p> <p>22 associated with a 33 percent greater</p> <p>23 likelihood of ADHD in children?</p> <p>24 MS. BROWN: I object to the</p> <p>25 form of the question.</p> |
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| <p>1 A. That's correct.</p> <p>2 Q. -- and stated they agreed with</p> <p>3 it, right?</p> <p>4 A. That's correct, yes.</p> <p>5 Q. And is it the consensus view of</p> <p>6 all of these authors who wrote the World</p> <p>7 Federation of ADHD International Consensus</p> <p>8 Statement that maternal use of acetaminophen</p> <p>9 during pregnancy is associated with a</p> <p>10 33 percent greater likelihood of ADHD in</p> <p>11 their children?</p> <p>12 MS. BROWN: I object to the</p> <p>13 form of that question.</p> <p>14 THE WITNESS: Okay. So let me</p> <p>15 just have -- I'm going to have to</p> <p>16 just -- to give you something -- to</p> <p>17 answer that more exactly, I need to</p> <p>18 look at something here.</p> <p>19 Okay. Okay. Let's go ahead</p> <p>20 and -- okay. Let me just look at your</p> <p>21 question again.</p> <p>22 MS. BROWN: He can repeat it,</p> <p>23 if you can't see it.</p> <p>24 THE WITNESS: So I just want to</p> <p>25 be accurate in how I refer to the</p> | <p>1 THE WITNESS: That's a</p> <p>2 Taiwanese study, correct.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. Was one of the evidence-based</p> <p>5 conclusions that was reached by the</p> <p>6 international consensus that there's a</p> <p>7 dose-response relationship between maternal</p> <p>8 prenatal use of acetaminophen and ADHD?</p> <p>9 MS. BROWN: Objection to the</p> <p>10 form.</p> <p>11 THE WITNESS: Can you point to</p> <p>12 the number you're looking at?</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. Next sentence. It's part of</p> <p>15 38, top of the right -- the right column top.</p> <p>16 A. Right column top, 38. That was</p> <p>17 the issues studied -- yes, that's included</p> <p>18 here as a -- and keep in mind that the --</p> <p>19 this is obviously reporting a very large</p> <p>20 series of findings. We're not doing a deep</p> <p>21 dive into one study. We're not talking about</p> <p>22 potential confounding, we're not talking</p> <p>23 about all of the issues that are the subject</p> <p>24 of my report.</p> <p>25 This is only, if you will, the</p> |

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| <p>1 top-level finding because we're trying to 2 point the people to studies that are -- to 3 meta-analyses and very large studies. 4 That's the goal here. It's meant to be a 5 resource for people to deep dive into these 6 issues. 7 It's not -- it's not meant to 8 assert -- none of this asserts that any of 9 these are causes. 10 In fact, if you look at just 11 before Item Number 34, it states 12 "environmental correlates of ADHD." That's 13 simply saying these are correlates that 14 people -- we think we would like the field to 15 know about. 16 Q. Was one of the evidence-based 17 conclusions about ADHD that was reached by 18 the international consensus that there's a 19 dose-response relationship between maternal 20 prenatal use of acetaminophen and ADHD? 21 MS. BROWN: Objection to the 22 form of the question. 23 THE WITNESS: So it's not a 24 conclusion. It's -- and I -- I have 25 to clarify. Maybe I didn't -- I think</p> | <p>1 conclusions then, right? 2 A. They're conclusions of the 3 authors of the studies, not conclusions of 4 the authors of the paper. 5 Q. Well, the -- what the paper did 6 is identify 208 conclusions that they 7 believed had strong evidence, right? 8 MS. BROWN: Objection to the 9 form. 10 THE WITNESS: Say that again. 11 208 -- 12 QUESTIONS BY MR. DOVEL: 13 Q. Conclusions that you and the 14 other authors believed had strong evidence? 15 A. Yeah -- yes, that's -- 16 MS. BROWN: Objection. 17 Objection to the form. 18 THE WITNESS: Yes. I'm sorry. 19 That is correct. 20 QUESTIONS BY MR. DOVEL: 21 Q. One of the conclusions that you 22 and the other authors concluded had strong 23 evidence was that there's a dose-response 24 relationship between maternal prenatal use of 25 acetaminophen and ADHD?</p> |
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| <p>1 I didn't say this, that the phrase 2 "consensus statement" is used in 3 different ways. 4 Sometimes people use it -- the 5 term "consensus statement to" say we 6 have a bunch of professionals, and 7 here are our opinions about something. 8 This is how we think you should treat 9 ADHD, et cetera. 10 This is a very -- it's very 11 clearly stated that we are just 12 listing findings that have been 13 reported in studies. It's not -- 14 we're not -- we're not drawing 15 conclusions from any one of these 16 studies or any collection of these 17 studies. 18 QUESTIONS BY MR. DOVEL: 19 Q. Then why did you title it "208 20 evidence-based conclusions"? 21 A. Because these are conclusions 22 that these authors of the individual -- each 23 item -- okay? These are conclusions that 24 were drawn from the authors of these studies. 25 Q. Okay. And these are</p> | <p>1 A. That's 38, yes. I see that. 2 Q. And that's still the published 3 consensus of the World Federation of ADHD, 4 right? 5 A. Well, again, I'm going to say 6 that it's -- it's not the consensus of the 7 World Federation of ADHD. It's the consensus 8 of the authors that wrote a statement. 9 That's what it is. 10 Q. Now, a dose-response 11 relationship is -- if there is an actual 12 dose-response relationship, that tells us 13 that exposure to that drug likely is a cause, 14 right? 15 MS. BROWN: Objection to the 16 form. 17 THE WITNESS: I would disagree 18 with that statement. 19 QUESTIONS BY MR. DOVEL: 20 Q. Well, if we increase the dose 21 and that increases the risk or the severity 22 that flows from it, it suggests a 23 relationship between the drug and the effect, 24 right? 25 MS. BROWN: Objection to the</p> |

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| <p>1 form.</p> <p>2 THE WITNESS: It doesn't mean</p> <p>3 that it's likely to cause. The</p> <p>4 dose-response relationship or I think</p> <p>5 biological gradient is -- as Bradford</p> <p>6 Hill refers to it, is one of nine</p> <p>7 criteria that Bradford Hill -- that</p> <p>8 the Bradford Hill method used to make</p> <p>9 a decision based on the totality of</p> <p>10 data about whether something should be</p> <p>11 a cause.</p> <p>12 QUESTIONS BY MR. DOVEL:</p> <p>13 Q. And one of the reasons we look</p> <p>14 at the dose-response relationship is because</p> <p>15 if there is a dose-response relationship,</p> <p>16 that suggests that it's not the result of</p> <p>17 confounding, right?</p> <p>18 MS. BROWN: I object to the</p> <p>19 form of that question.</p> <p>20 THE WITNESS: Well, no, I</p> <p>21 totally disagree with that,</p> <p>22 absolutely. In fact, there are --</p> <p>23 there are -- I believe it's the</p> <p>24 Bandoli paper that shows that</p> <p>25 there's -- that there is confounding</p> | <p>1 MS. BROWN: Object to the form.</p> <p>2 THE WITNESS: Yes, I see that.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. This right here is sometimes</p> <p>5 referred to as genetic transmission, right?</p> <p>6 A. Correct.</p> <p>7 Q. Now, another potential way this</p> <p>8 could happen is that the genes could</p> <p>9 encourage acetaminophen use, which could</p> <p>10 cause ADHD, right?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form of the question.</p> <p>13 THE WITNESS: I don't</p> <p>14 understand how genes are encouraging</p> <p>15 acetaminophen use.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. Well, if genes -- if there were</p> <p>18 genes that caused certain people to use more</p> <p>19 acetaminophen and the acetaminophen caused</p> <p>20 the ADHD, that's what this pathway would look</p> <p>21 like, the second one I've drawn, right?</p> <p>22 MS. BROWN: I object to the</p> <p>23 form of the question.</p> <p>24 THE WITNESS: But that's --</p> <p>25 what's -- it's not -- that's not the</p> |
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| <p>1 of dose -- of dose response that women</p> <p>2 who uses acetaminophen at higher -- at</p> <p>3 higher doses are more likely to have</p> <p>4 mental illness -- mental illnesses</p> <p>5 than women who use lower doses.</p> <p>6 So dose -- dose-response</p> <p>7 analysis are not protected from</p> <p>8 confounding.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Okay. Let's draw a diagram</p> <p>11 here, so back to our ELMO.</p> <p>12 Let's start with genetics up</p> <p>13 here at the top of the diagram. And we've</p> <p>14 got ADHD down here. And I've got</p> <p>15 acetaminophen over here.</p> <p>16 MS. BROWN: Object to the</p> <p>17 demonstrative.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Okay. You see what I've drawn</p> <p>20 here?</p> <p>21 A. I do, yes.</p> <p>22 Q. Okay. This would be a</p> <p>23 circumstance where genetics is serving as a</p> <p>24 confounder causing both acetaminophen use and</p> <p>25 ADHD use, right?</p> | <p>1 hypothesis -- well, it's not -- that's</p> <p>2 not what I'm talking about in my</p> <p>3 report.</p> <p>4 I'm talking about that the</p> <p>5 genes that predisposed to ADHD cause</p> <p>6 mothers to -- some mothers to have</p> <p>7 ADHD. Those mothers with ADHD are</p> <p>8 more likely to use acetaminophen, and</p> <p>9 then obviously they're more likely to</p> <p>10 have children with ADHD.</p> <p>11 QUESTIONS BY MR. DOVEL:</p> <p>12 Q. When you have this situation,</p> <p>13 this is called either nurture transition</p> <p>14 {sic} or environmental transmission, right?</p> <p>15 MS. BROWN: I object to the</p> <p>16 writing on this demonstrative, and I</p> <p>17 object to the form of the question.</p> <p>18 THE WITNESS: I'm not familiar</p> <p>19 with the term "nurture transmission."</p> <p>20 I -- what you're -- what it -- the</p> <p>21 arrow shows simply is -- and is</p> <p>22 that -- the hypothesis that</p> <p>23 acetaminophen is causing ADHD.</p> <p>24 (Faraone Exhibit 755 marked for</p> <p>25 identification.)</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Let's take a look at</p> <p>3 Exhibit 755. This is the Pingault 2021</p> <p>4 study.</p> <p>5 I'm going to look at just one</p> <p>6 specific part of this. You see in the</p> <p>7 abstract it talks that they investigated</p> <p>8 "genetic transmission and genetic nurture,</p> <p>9 environmentally mediated effects"?</p> <p>10 MS. BROWN: I object to the</p> <p>11 form of the question.</p> <p>12 THE WITNESS: I do see that,</p> <p>13 yes.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. And one of the results is that</p> <p>16 "The maternal polygenic risk score for</p> <p>17 neuroticism remained associated with ADHD</p> <p>18 ratings, even after adjusting for the child</p> <p>19 polygenic score, indicating genetic nurture."</p> <p>20 Do you see that?</p> <p>21 A. Maternal polygenic score. I do</p> <p>22 see that, yes, I --</p> <p>23 Q. And that means the ADHD risk</p> <p>24 was not being transmitted genetically from</p> <p>25 the mother to the child; it was instead being</p> | <p>1 THE WITNESS: Yeah. It's --</p> <p>2 I see. This is not talking about a</p> <p>3 specific environmental effect. It's</p> <p>4 talking -- it's using trio studies. I</p> <p>5 see. Okay.</p> <p>6 So it's -- it's concluding that</p> <p>7 there's some -- apparently some</p> <p>8 unknown genetic nurture that's</p> <p>9 occurring.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. Well, let's go back to my ELMO</p> <p>12 picture here.</p> <p>13 Are you aware of any study</p> <p>14 that's concluded that while there are some</p> <p>15 ADHD genes that are also associated with</p> <p>16 acetaminophen, and the result is that it</p> <p>17 transmits genetically A -- the ADHD risk;</p> <p>18 it's not transmitted through a nurture</p> <p>19 mechanism?</p> <p>20 MS. BROWN: I object to the</p> <p>21 form of the question.</p> <p>22 THE WITNESS: I don't -- I</p> <p>23 don't know of any study that's applied</p> <p>24 the nurture -- genetic nurture</p> <p>25 paradigm to the question of</p> |
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| <p>1 transmitted through an environmental impact,</p> <p>2 right?</p> <p>3 MS. BROWN: Objection to the</p> <p>4 form of the question.</p> <p>5 THE WITNESS: I think what it's</p> <p>6 stating here is that the mother's</p> <p>7 genetics are affecting the -- perhaps</p> <p>8 the home environment that's having an</p> <p>9 effect on the child.</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. It could be the home</p> <p>12 environment could be causing the mother to</p> <p>13 take more acetaminophen, right?</p> <p>14 MS. BROWN: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: I don't -- are</p> <p>17 they addressing acetaminophen? I</p> <p>18 don't believe they're addressing --</p> <p>19 this paper is about acetaminophen, so</p> <p>20 we really can't --</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. It doesn't tell us what the</p> <p>23 environmental effect is, right?</p> <p>24 MS. BROWN: Let him finish,</p> <p>25 please. Let's let him finish.</p> | <p>1 acetaminophen.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. So there's no basis to conclude</p> <p>4 that if there are autism genes associated</p> <p>5 with taking acetaminophen, that that means</p> <p>6 genetics is confounding acetaminophen</p> <p>7 studies, right?</p> <p>8 MS. BROWN: Objection to the</p> <p>9 form.</p> <p>10 Did -- you meant to ask about</p> <p>11 autism or to ADHD?</p> <p>12 MR. DOVEL: Oops, let me</p> <p>13 rephrase it.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. There's no basis to conclude</p> <p>16 that if genetics is -- if -- withdrawn.</p> <p>17 There's no basis to assume that</p> <p>18 if ADHD genes are associated with taking</p> <p>19 acetaminophen, that that means that those</p> <p>20 genes are confounding the studies that show a</p> <p>21 relationship between acetaminophen and ADHD,</p> <p>22 right?</p> <p>23 MS. BROWN: I object to the</p> <p>24 form of that question.</p> <p>25 THE WITNESS: No, I -- I</p> |

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| <p>1 disagree with that. 2 QUESTIONS BY MR. DOVEL: 3 Q. Did those studies rule out that 4 the mechanism wasn't through -- causing more 5 acetaminophen use which then increases the 6 ADHD? 7 MS. BROWN: Objection to the 8 form. 9 THE WITNESS: It's a 10 speculate -- what you're saying is a 11 total speculation. 12 Right now what we know is that 13 the genetic risk for ADHD predicts -- 14 is associated with maternal use of 15 acetaminophen during pregnancy. 16 QUESTIONS BY MR. DOVEL: 17 Q. Do we know whether the 18 mechanism is direct genetic transmission, or 19 is it in part genetics through acetaminophen 20 that transmits the risk? 21 MS. BROWN: I object to the 22 form of the question. 23 THE WITNESS: Well, the only 24 thing we have solid evidence on is 25 that there's a genetic association</p> | <p>1 maternal ADHD, and they all three did a -- 2 what I would say is a very bad job of it. 3 Two of the studies used a 4 six-item screening questionnaire that is not 5 meant to diagnose ADHD. It's meant to -- 6 it's meant for screening for ADHD in adults, 7 in clinics. It's six -- it's basically six 8 items. 9 It does not include any of the 10 DSM impairment criteria any of the criteria 11 from multi-situationality. It's been shown 12 to have very poor -- in population samples in 13 particular, it's a very -- it's a very poor 14 proxy for the diagnosis of ADHD. So it's two 15 of the studies. 16 The third study I believe was 17 Baker. Baker did a mix of -- what was it -- 18 a mix -- he did a mix of medical records and 19 may have had a questionnaire in a sub-sample 20 and reports in the paper that he did a 21 separate analysis of that sub-sample. 22 And just -- all he says is the 23 point estimate didn't change but never 24 actually presents the data, which it's very 25 hard to evaluate actually what happened</p> |
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| <p>1 with acetaminophen, and there's -- I'm 2 sorry. Let's back up a second. 3 We know that the genetic risk 4 for ADHD causes obviously ADHD in 5 mothers and that mothers who have ADHD 6 transmit ADHD to their offspring, and 7 they're also more likely to use -- if 8 they have the genetic risk for ADHD, 9 they're also more likely to use 10 acetaminophen. 11 So that's what's known. The 12 nurture transmission arrow is just -- 13 it's speculation. 14 QUESTIONS BY MR. DOVEL: 15 Q. Well, the epidemiology studies 16 have looked at the question of whether or not 17 a neurodevelopmental disorder -- ADHD or 18 other neurodevelopmental disorder of a mother 19 is a confounder, right? They've adjusted for 20 that? 21 A. Let me just read the question 22 again. 23 Oh, no, no. The epidemiologic 24 studies about acetaminophen, I believe there 25 are three that made an attempt to adjust for</p> | <p>1 because the data -- typically when someone 2 does something like that, it's nice to have 3 the data actually presented in the supplement 4 or somewhere, but it's hard to evaluate 5 exactly what he did because it's not there. 6 So these are three studies that 7 looked at mat -- that adjusted -- that 8 attempted to -- I guess it was -- I think it 9 was Liew that used the ASRS, and even though 10 he did find that the odds ratio decreased 11 somewhat when he -- even using this poor 12 measure of maternal ADHD. 13 And -- but what I would like 14 him to do -- I don't know -- I don't 15 understand why such a poor measurement was 16 used. It would be much better to have a 17 diagnosis of ADHD from the Danish Medical 18 Registries or -- although that might be 19 difficult to get for all sorts of reasons. 20 But anyway, so I guess to 21 answer your question, no, I don't think we 22 can say that those epidemiologic studies have 23 adjusted for maternal ADHD. 24 Q. Well, they certainly in -- as 25 part of their efforts, they did things that</p> |

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| <p>1 they thought would test that, right? You</p> <p>2 don't agree with how they did it, right?</p> <p>3 A. I'm just saying three, but</p> <p>4 you're talking about three of the studies,</p> <p>5 right?</p> <p>6 Q. Liew, Baker --</p> <p>7 A. Liew, Baker and --</p> <p>8 Q. -- and Chen?</p> <p>9 A. I forget who the third one was.</p> <p>10 Q. Well, regardless of what it</p> <p>11 was --</p> <p>12 A. Forget who they are, right,</p> <p>13 right.</p> <p>14 Q. -- there were three that did</p> <p>15 it, and you're not satisfied with how they</p> <p>16 did it?</p> <p>17 A. Yeah. I'm saying that they did</p> <p>18 a very bad job of it. It's not -- yes.</p> <p>19 That's -- they didn't -- they didn't -- they</p> <p>20 didn't -- they didn't even use all the DSM</p> <p>21 symptoms.</p> <p>22 They used six -- I mean, the</p> <p>23 two studies that use the -- it's called the</p> <p>24 ASRS, the Adult Self-Report Scale. They just</p> <p>25 used six -- they just used six symptoms and a</p> | <p>1 MS. BROWN: Well, look at your</p> <p>2 question.</p> <p>3 THE WITNESS: I'm trying --</p> <p>4 MS. BROWN: I mean, he's</p> <p>5 answering it. Finish your question.</p> <p>6 THE WITNESS: I'm trying to</p> <p>7 communicate that I know a lot about</p> <p>8 the ASRS because having been part of</p> <p>9 the development team, I know exactly</p> <p>10 what it is.</p> <p>11 It's something, for example, I</p> <p>12 think is useful for screening for ADHD</p> <p>13 in adults, particularly in -- I --</p> <p>14 I -- I encourage primary care doctors</p> <p>15 to use it when they think someone</p> <p>16 might have ADHD, but it is in no way</p> <p>17 meant to replace a diagnosis.</p> <p>18 So it's an -- it's an -- it's</p> <p>19 an extremely noisy measure, and</p> <p>20 noisy measures are a problem when</p> <p>21 you're adjusting because if you're</p> <p>22 adjusting something for a noisy</p> <p>23 measure, it's -- you're not going to</p> <p>24 get the full adjustment.</p> <p>25 You're going to get maybe a</p> |
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| <p>1 cutoff that was -- I know about the ASRS. I</p> <p>2 was part of the development team. I played a</p> <p>3 small roll in the development team. It's</p> <p>4 not --</p> <p>5 Q. There's no reasonable theory</p> <p>6 under which --</p> <p>7 MS. BROWN: Wait, wait, wait.</p> <p>8 You interrupted him.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. -- could have skewed the</p> <p>11 results, right?</p> <p>12 MS. BROWN: I'm sorry, sir, you</p> <p>13 interrupted him.</p> <p>14 THE WITNESS: Wait. No, no.</p> <p>15 MS. BROWN: Hold on.</p> <p>16 THE WITNESS: Okay.</p> <p>17 MS. BROWN: Hold on. Let's get</p> <p>18 the -- let's get the rest --</p> <p>19 MR. DOVEL: He's going on to</p> <p>20 talk about the development of S- --</p> <p>21 ASRS --</p> <p>22 MS. BROWN: No, he's</p> <p>23 answering --</p> <p>24 MR. DOVEL: -- which is</p> <p>25 irrelevant.</p> | <p>1 partial adjustment or nothing at all.</p> <p>2 Now, Liew got a partial adjustment,</p> <p>3 but not -- my expectation's that he</p> <p>4 would have gotten a better adjustment</p> <p>5 if he had used -- actually used</p> <p>6 diagnoses.</p> <p>7 QUESTIONS BY MR. DOVEL:</p> <p>8 Q. Let's take a look at our</p> <p>9 consensus statement, page 794.</p> <p>10 A. Okay. Yes.</p> <p>11 Q. And fact number 18. "Many</p> <p>12 large epidemiological studies show that ADHD</p> <p>13 often co-occurs with other psychiatric</p> <p>14 disorders, especially," and then there's a</p> <p>15 list.</p> <p>16 The list includes autism</p> <p>17 spectrum disorder, right?</p> <p>18 A. Uh-huh.</p> <p>19 Q. And conclusion number 32,</p> <p>20 "Genetic and environmental influences are</p> <p>21 partially shared between ADHD and many other</p> <p>22 psychiatric disorders, including autism</p> <p>23 spectrum disorder."</p> <p>24 Right?</p> <p>25 A. Yes, that's correct.</p> |

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| <p>1 Q. Do you agree that environmental 2 influences are partially shared between ADHD 3 and autism spectrum disorder? 4 A. That's -- that is -- I don't 5 believe we have -- I don't believe the 6 consensus statement covers -- found anything 7 about that at all. 8 Q. Well, when it says -- 9 A. Is that right? 10 Q. -- in number 32, "Genetic and 11 environmental influences are partially shared 12 between ADHD and many other psychiatric 13 disorders, e.g.," and then it lists autism -- 14 autism spectrum disorder. 15 Shouldn't we read that as 16 saying that environmental influences are 17 partially shared between ADHD and ASD? 18 A. Ah, I see. Okay. Yes, I 19 understand -- I understand here. 20 So it's the -- yeah. The 21 shared environmental risk part of this is 22 referring to inferences that come from twin 23 studies as opposed to inferences that come 24 from exposure epidemiology. 25 So that's what that's based</p> | <p>1 consensus statement says, do you agree that 2 the consensus statement says that ADHD and 3 autism spectrum disorder share environmental 4 causes? 5 A. It actually doesn't -- it 6 actually doesn't say that explicitly, does 7 it? 8 Q. Well, it says genetic and 9 environmental influences. 10 Do you see that? 11 A. Well, what I'm -- all I'm 12 saying is to be accurate is that it -- it 13 doesn't exactly say that. It's saying that 14 genetic and environmental influences -- it's 15 written in a somewhat staccato style. I'd 16 have to look at the exact paper to know. 17 I do know that those papers are 18 not about -- not about exposure epidemiology. 19 They're not about acetaminophen. They're 20 about -- probably the only environmental 21 information would be from twin studies. 22 Q. Let's talk about what these 23 words say here. 24 When it says, "Genetic and 25 environmental influences," are they talking</p> |
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| <p>1 upon. Twin studies can not only tell us if 2 the environment is -- as you know, twin 3 studies of both ADHD and autism show that 4 there's an environmental piece to those 5 disorders. 6 And they also suggest that 7 there's some overlap in genetic risks and 8 the as-yet unknown environmental, but they 9 don't specify what those environmental causes 10 actually are because they haven't -- they 11 haven't been discovered. 12 And this last sentence here, 13 what I don't -- would have to go -- do a 14 deeper dive into the reference section here. 15 It's basically saying that when there's 16 evidence for these overlapping risks, that 17 means that they likely share pathways. But I 18 would have to do a deeper dive into the 19 papers to clarify the actual ADHD -- autism 20 overlap regarding the environmental 21 influences, because I haven't looked closely 22 at that in quite a long time. 23 Q. Well, we're going to look at 24 that a little more closely. 25 But just in terms of what the</p> | <p>1 about genetic and environmental causes? 2 MS. BROWN: Objection to the 3 form. 4 THE WITNESS: So the DNA 5 studies are talking about -- well, to 6 some degree -- well, the family and 7 twin studies are talking -- if -- the 8 twin studies are the ones that make -- 9 well, some of the family studies can 10 contribute to this as well. So let's 11 just say, it's the -- it's the family 12 and twin studies that would contribute 13 information about shared environmental 14 causes, and these are mathematical 15 abstractions very much like the 16 heritability coefficient, when we say 17 that a certain percentage of variants 18 is due to environment; they're not any 19 specific environmental exposure or 20 cause. 21 QUESTIONS BY MR. DOVEL: 22 Q. I didn't ask about specific. 23 A. Well, I'm just -- I know -- I 24 understand that, but I'm just trying to 25 explain.</p> |

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| <p>1 Q. Well, I just want to get an 2 answer to my question, which is, in the 3 consensus statement when it says genetic and 4 environmental influences, they're talking 5 about genetic and environmental causes, 6 right? 7 A. Yes. 8 MS. BROWN: Objection to the 9 form. 10 THE WITNESS: But, again, what 11 is unclear, as I'm reading this, is 12 whether -- it doesn't -- in some cases 13 ADHD shares genetic influences with 14 some of these disorders, in some cases 15 it shares environmental influences, in 16 some cases it likely shares both. 17 I don't know exactly what the 18 result is for autism spectrum 19 disorders because it's not stated 20 here. 21 And so to know that, we'd have 22 to do a deeper dive into the relevant 23 paper. 24 QUESTIONS BY MR. DOVEL: 25 Q. Well, if we -- we're going to</p> | <p>1 Okay. I mean, if we -- if we -- it says what 2 the sentence says. It doesn't say what you 3 said. You said something different than what 4 the sentence says. 5 Q. Well, it says -- well, how did 6 I say something different? What part did I 7 get wrong? 8 A. Because it's talking about -- 9 it's saying that genetic and environmental 10 influences are partially shared between ADHD 11 and many other disorders. So for some of 12 these disorders -- it's not saying for all of 13 these disorders genetic and environmental 14 influences are shared. It's saying that for 15 some it could just be genetics, for some it 16 could just be just environment, and for some 17 it could be both, and all I'm saying is if we 18 look at the relevant paper, we would get the 19 answer to that question. 20 Q. So you're reading the word 21 "and" as and/or? 22 MS. BROWN: Objection to the 23 form. 24 THE WITNESS: I am just 25 reading -- I'm just reading what's</p> |
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| <p>1 look at a paper you wrote. You wrote a paper 2 on that exact subject, didn't you, in 2015? 3 And you concluded that autism and ADHD share 4 environmental risk factors, right? 5 A. Why don't you pull that paper 6 up and take a look at what I said. 7 Q. Happy to do that, but let's 8 finish here. 9 A. Okay. 10 Q. The consensus statement -- back 11 up. 12 Just to be clear, when it says, 13 "Environmental influences," the word 14 "influences," we're talking about causes of 15 ADHD, right? 16 MS. BROWN: Objection to the 17 form. 18 THE WITNESS: This is talking 19 about causes, yes. 20 QUESTIONS BY MR. DOVEL: 21 Q. And what it says is that these 22 various types of studies show that genetic 23 and environmental causes are partially shared 24 between ADHD and autism? 25 A. No, it's not saying that.</p> | <p>1 written there, and I am telling you 2 what my -- I'm not trying to argue 3 with you or saying you're wrong. I'm 4 just saying the answer is -- we can 5 find the answer if we look at the 6 appropriate paper. I don't have to 7 guess about it. Because I would 8 rather not guess. 9 QUESTIONS BY MR. DOVEL: 10 Q. Evidence of shared genetic and 11 environmental risks among disorders suggests 12 that these disorders also share a 13 pathophysiology, right? 14 A. That's what it says, yes. 15 Q. And that was more than just 16 what it says. That was the consensus of the 17 authors of the international consensus, 18 right? 19 A. That is correct, yes. Yes. 20 Q. It was your conclusion as well, 21 right? 22 A. That is correct, yes. 23 Q. It was your conclusion that the 24 evidence of shared genetic and environmental 25 risks among disorders would suggest that the</p> |

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| <p>1 disorders also have biological pathways that 2 they share in causing the diseases, right? 3 A. And to be clear, when we -- 4 when we say here that there are shared 5 pathophysiology or shared biological 6 pathways, we're not saying that the entire 7 pathophysiology is shared or that the 8 entire -- all biological pathways are shared. 9 What we're saying is that our best bet is 10 that when we finally, you know, are at the 11 end phase of discovery, some of the pathways, 12 some of the pathophysiology will be -- will 13 be shared. That's the -- that's kind of the 14 hope. 15 But it's very likely that -- 16 it's very likely that much of that is not 17 shared. We know that from, for example, the 18 brain imaging studies of ADHD and autism that 19 the INMA consortium has done that -- I mean, 20 I published a paper basically showing that 21 for the structural brain differences, the 22 correlation between ADHD and autism findings 23 was essentially zero. 24 Q. Do you agree, sir, that there 25 are biological pathways that dysregulate</p> | <p>1 pathways, we should find some -- we should 2 find some sharing there. 3 That type of sharing hasn't 4 come out strongly in the -- in the structural 5 brain imaging data, but I still think it's a 6 reasonable hypothesis for people to continue 7 to test in other -- in other studies. 8 (Faraone Exhibit 768 marked for 9 identification.) 10 QUESTIONS BY MR. DOVEL: 11 Q. Let's take a look at 12 Exhibit 768. This is the Faraone April 13 '21 -- April '21 tweet. 14 A. Yeah. It's the one on the 15 computer here? 16 Q. Yeah. 17 Is Exhibit 768 a set of social 18 media posts that you posted or responded to 19 on April 17, 2021? 20 A. Yes. 21 Q. You said you were happy to 22 report that the International Consensus 23 Statement on ADHD was the most downloaded 24 article from Neuroscience & Biobehavioral 25 Reviews in the past 90 days, right?</p> |
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| <p>1 neurodevelopment and create brain variations 2 that lead to ADHD? 3 MS. BROWN: Objection to the 4 form. 5 THE WITNESS: I think that is a 6 very reasonable hypothesis that I 7 encourage people to explore. 8 QUESTIONS BY MR. DOVEL: 9 Q. Do you agree that some of those 10 pathways, those biological pathways, are 11 shared between ADHD and autism? 12 A. That is another hypothesis that 13 I would -- I would support in terms of 14 getting further research. 15 Q. Well, this doesn't say here we 16 need to do further research on it; this is 17 presented as a conclusion, right? 18 A. No, I think the word "suggests" 19 is in there, right? This is suggests. This 20 is all about what -- look, what I'm saying is 21 if we know that there's shared causes, what 22 we do as scientists, we say, what does -- 23 what does that predict? Okay. It predicts 24 or suggests the hypothesis that when we look 25 into pathophysiology, we look into biological</p> | <p>1 A. That is exactly what it says, 2 correct. 3 Q. And then the following page, 4 there's a post from you responding on 5 January 11, 2022. It says you're loving the 6 interest in the International Consensus 7 Statement? 8 A. Correct, and I report what 9 languages it's been translated into. 10 Q. And then on February 11, you 11 state, "Help fight stigma and misinformation 12 about ADHD by disseminating the International 13 Consensus Statement"? 14 A. That is correct. 15 Q. You agree that the 16 International Consensus Statement is a good 17 way to fight misinformation about ADHD? 18 A. I do. 19 (Faraone Exhibit 769 marked for 20 identification.) 21 QUESTIONS BY MR. DOVEL: 22 Q. Let's take a look at 769. 23 This is from the ADHD Evidence 24 Project web page. 25 First page we'll look at. Do</p> |

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| <p>1 you recognize this as a portion of your ADHD 2 Evidence Project? 3 A. I do. 4 Q. And this is what you see, if 5 you click on the evidence tab on the ADHD 6 Evidence Project, right? 7 A. Let me just think about that. 8 So I believe that's correct, yeah. 9 Q. Near the bottom right you 10 highlight five conclusions from the ADHD 11 Evidence Project, right? 12 A. That is correct. There are 13 five bullet points here. 14 Q. And the second one relates to 15 causes of ADHD, right? 16 A. That's correct. 17 Q. And what you highlight is that, 18 "Most cases of ADHD are caused by the 19 combined effects of many genetic and 20 environmental risks." 21 Right? 22 A. Correct. 23 Q. And if we turn the page over, 24 you see something that appears on the home 25 page of your website. This is part of a</p> | <p>1 A. That's another statement 2 that's -- yes. 3 Q. Let's take a look at 4 Exhibit 784, the Khoury article. We looked 5 at that a little earlier. And let's go to 6 page 345. 7 MS. BROWN: Do you have that? 8 I think we're going back to 784. 9 MR. DOVEL: It's 784, yeah. 10 I've got it on the screen here. 11 THE WITNESS: It's a consensus 12 statement or something else? 13 MS. BROWN: Wait, wait. Let's 14 get you the hard copy. It looks like 15 it's -- 16 THE WITNESS: It's hard to read 17 this thing here. 18 MS. BROWN: Yeah, yeah. Hold 19 on. It was marked. 20 QUESTIONS BY MR. DOVEL: 21 Q. You can zoom in a bit on that 22 etiology paragraph. 23 MS. BROWN: Did you just -- 24 hold on. 25 Did you just mark it, Counsel?</p> |
| Page 398 | Page 400 |
| <p>1 banner that scrolls, and one of the things 2 that pops up is this quote from the 3 International Consensus Statement that 4 appears here, right? 5 A. That is correct, yes. 6 (Faraone Exhibit 772 marked for 7 identification.) 8 QUESTIONS BY MR. DOVEL: 9 Q. Let's look at Exhibit 772. 10 This is from the World Federation of ADHD 11 website. 12 This is from the World 13 Federation of ADHD website where they have a 14 section on their consensus statement, right? 15 A. Okay. 16 Q. And if you look down in the 17 second paragraph there, the second sentence, 18 it says, "The authors highlight that most 19 cases of ADHD are caused by the combined 20 effects of many genetic and environmental 21 risks." 22 Right? 23 A. That's correct. 24 Q. It's another statement of what 25 the authors are highlighting, right?</p> | <p>1 MR. DOVEL: No, it was done 2 earlier this morning. 3 MS. BROWN: Okay. Let's just 4 take a minute and get you your copy. 5 QUESTIONS BY MR. DOVEL: 6 Q. On page 345 -- 7 MS. BROWN: He doesn't have his 8 copy yet. Yeah, neither of us seem to 9 be able to -- 10 MR. DOVEL: Yeah. I'm asking a 11 question. You can object. 12 MS. BROWN: Okay. I just want 13 to get him a copy. You asked for it. 14 QUESTIONS BY MR. DOVEL: 15 Q. On page 345, you have a section 16 on etiology, right? 17 MS. BROWN: Take a minute. 18 Here's the hard copy. 19 THE WITNESS: Okay. 345. 20 Yes. 21 QUESTIONS BY MR. DOVEL: 22 Q. And what's on the screen is 23 identical to the paper that you have in front 24 of you? 25 A. It -- from a quick cursory</p> |

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| <p>1 glance, it looks like it's the same thing. 2 Yes. 3 Q. One of the things -- and this 4 article is published in 2022, right? 5 A. That's -- where is that? It's 6 reason for sure -- yeah, 2022. 7 Q. One of the things you write 8 here is, again, the statement that "ADHD is 9 most commonly caused by the cumulative 10 effects of many genetic and environmental 11 risks, each of which usually exerts a small 12 individual effect." 13 Right? 14 A. That is the hypothesis which I 15 have endorsed for quite a while. 16 Q. Then you identify environmental 17 risk factors, right? 18 A. Correct. 19 Q. You say that "Many 20 environmental events have been found to 21 increase the risk for ADHD or ADHD symptoms." 22 Then it says, "As reviewed by 23 Faraone and colleagues." 24 That's a reference to the 25 International Consensus Statement, right?</p> | <p>1 I said, I don't know if people reading this 2 are part of a lay audience, they may not 3 understand what it means. So I'm just trying 4 to clarify when you use that term, that it 5 does not mean cause. 6 Q. The term -- 7 A. Because it can be 8 misinterpreted as cause. 9 Q. The term you chose to use here 10 was what? 11 A. The term -- the heading reads 12 "Environmental Risk Factors." 13 Q. You write that "The strongest 14 evidence is for," and then say, "Exposure 15 during the fetal period to maternal smoking, 16 acetaminophen, valproate," and so on. 17 Right? 18 A. I see that, yes. 19 Q. And that was true? 20 A. Yes. Yes. It's -- they're 21 listed in the consensus statement. 22 Q. And you published it, then, 23 after the consensus statement in your 2022 24 article, right? 25 A. That's correct. Yes.</p> |
| Page 402 | Page 404 |
| <p>1 A. Let's see. 37 is -- 37 is 2 indeed the International Consensus Statement. 3 And, of course, we're talking about 4 environmental risk factors, meaning 5 correlates as opposed to known causes. 6 Q. What you wrote here was that -- 7 well, what you titled this subsection was 8 Environmental Risk Factors, right? 9 A. I'm just clarifying as I have 10 before that risk factors -- that term means 11 correlates, not causes. 12 Q. It means the same thing as 13 correlates; they're synonyms? 14 A. They're synonyms, correct. 15 Q. So we can use the term "risk 16 factors," right? 17 MS. BROWN: Objection to the 18 form. 19 THE WITNESS: You can use 20 whatever term you would like to use, 21 yes. 22 QUESTIONS BY MR. DOVEL: 23 Q. Well, the term you chose to use 24 was what? 25 A. I'm just clarifying because, as</p> | <p>1 Q. Your article was peer-reviewed? 2 A. This article was -- yeah, this 3 was peer-reviewed. This is -- let me just 4 double-check to make sure it's a journal 5 article. 6 Yes, it's a -- yes, it's -- 7 yeah -- yes, it was peer-reviewed. 8 Q. Now, you're familiar with 9 valproate? 10 A. I am. 11 Q. It's sometimes sold under the 12 brand name of Depakote? 13 A. That's my understanding. 14 Q. Valproate is associated with 15 higher incidence of autism? 16 MS. BROWN: Objection to the 17 form. 18 THE WITNESS: I don't know a 19 lot about autism. I'm focusing mostly 20 on ADHD. That rings a bell that 21 it's -- but I just don't know the 22 details about that. 23 QUESTIONS BY MR. DOVEL: 24 Q. Well, you read the materials in 25 this case, including the expert reports of</p> |

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| <p>1 plaintiffs. They quoted the label for 2 Depakote that it warns that valproate causes 3 autism, right? 4 MS. BROWN: Hold on. Objection 5 to the form of the question. 6 THE WITNESS: Yeah. So I was 7 not reading the autism section of 8 anybody's documents. 9 QUESTIONS BY MR. DOVEL: 10 Q. If we go over to page 350, you 11 created a chart describing the maternal 12 factors that increased the risk of ADHD in 13 offspring, right? 14 A. Okay. 350. Okay. Yeah, these 15 are -- I see this. 16 I mean, yes, so we're 17 essentially reporting the same environmental 18 correlates that we talked about in the 19 consensus statement. 20 Q. Now, because these exposures 21 during fetal development are associated with 22 ADHD risk, you would agree that pregnant 23 women should be warned about them, right? 24 MS. BROWN: I object to the 25 form of the question.</p> | <p>1 Part of this article -- I 2 believe this is the one that's -- partly has 3 a focus on health care to -- what's called 4 structural disparities or health care 5 disparities that occur in the United States 6 and trying to -- and trying to make the point 7 that prenatal care is essential for 8 everybody, including those who live in 9 poverty. 10 Q. Let's not talk about 11 generalities. Let's be concrete. 12 If we're talking about 13 acetaminophen exposure during pregnancy, one 14 way to minimize that exposure is to tell 15 pregnant women that they should limit their 16 use of acetaminophen, right? 17 MS. BROWN: All right. Hold 18 on. I object to the form of the 19 question. 20 THE WITNESS: It -- I don't see 21 where I say -- or I don't see where we 22 say that pregnant women should limit 23 use of acetaminophen. 24 QUESTIONS BY MR. DOVEL: 25 Q. I just need an answer to my</p> |
| Page 406 | Page 408 |
| <p>1 THE WITNESS: No, I don't agree 2 with that. I don't believe we say 3 that here. 4 QUESTIONS BY MR. DOVEL: 5 Q. Well, if we look at page 349 -- 6 A. 349. 7 Q. -- second paragraph from the 8 bottom, second sentence, it's highlighted. 9 You write, "Because many of the environmental 10 causes of ADHD are exposures during fetal 11 development, improved care for pregnant women 12 is essential, especially for those living in 13 poverty." 14 Right? 15 A. So this is a -- essentially a 16 generic statement, that there have been -- if 17 we look at the epidemiologic literature, 18 there have been many environment -- there 19 have been many correlates that have been 20 recorded. 21 Many of these are exposures 22 during pregnancy. We don't know which ones 23 are causal and which ones aren't, and it just 24 says that better prenatal care is a good 25 idea, especially for those living in poverty.</p> | <p>1 question. 2 Do you agree with it or not? 3 MS. BROWN: I -- same objection 4 and to the same question. 5 QUESTIONS BY MR. DOVEL: 6 Q. I'll ask you again, sir. 7 One way to limit the risk of 8 acetaminophen exposure to women -- withdrawn. 9 One way to limit the risk of 10 acetaminophen exposure during fetal 11 development would to -- would be to advise 12 pregnant women that they should limit their 13 use of AD -- of acetaminophen, right? 14 MS. BROWN: I object to the 15 form of the question. 16 THE WITNESS: So because 17 acetaminophen -- in my conclusions, I 18 conclude that acetaminophen is not 19 causal, is not a cause of ADHD. 20 Changing acetaminophen use during 21 pregnancy shouldn't have any effect on 22 ADHD. 23 QUESTIONS BY MR. DOVEL: 24 Q. Well, if we follow what's 25 reported here in the consensus statement in</p> |

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| <p>1 the Khoury paper, it is a risk, right? It's 2 one the risks with the strongest evidence, 3 right?</p> <p>4 MS. BROWN: No. Objection to 5 the form of the question.</p> <p>6 THE WITNESS: It's a correlate 7 of -- it's -- it is a correlate of 8 A -- of ADHD. It is -- is one of 9 several areas of investigation that 10 people have been pursuing to try to 11 understand the environment.</p> <p>12 The -- many of us in the field 13 would love to see a well-documented 14 environmental cause of ADHD that is 15 modifiable. That would be great.</p> <p>16 Unfortunately, we haven't, you 17 know, gotten there yet unless we 18 think, I suppose, that some degree of 19 traumatic brain injury is modifiable, 20 but it's more difficult. But we just 21 never -- we're not there yet.</p> <p>22 So since we don't have -- we 23 can't -- we're not making any 24 recommendations about any specific -- 25 any of these specific things</p> | <p>1 just means statistically significant 2 association that I -- I don't remember 3 the exact -- whether this was about 4 the meta-analysis or something else.</p> <p>5 But essentially it just means a 6 statistically significant association. 7 That's, in my view, not enough to make 8 any causal conclusions, and -- which, 9 of course, is the conclusion of 10 this more detail -- this obviously 11 much more detailed report that I did 12 here.</p> <p>13 QUESTIONS BY MR. DOVEL: 14 Q. Well, you say here that 15 "because many of the environmental causes of 16 ADHD are exposures during fetal development, 17 improved care for pregnant women is 18 essential."</p> <p>19 If we are going to provide 20 improved care for pregnant women with respect 21 to these environmental exposures, that means 22 limiting the exposures, right?</p> <p>23 MS. BROWN: No. I'll object to 24 the form of the question. 25 MR. DOVEL: Why did you answer</p> |
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| <p>1 because with -- except for the generic 2 comment about better prenatal care, 3 which is just good for everybody. 4 Because we don't have, as regards to 5 acetaminophen for sure, evidence that 6 supports a causal conclusion.</p> <p>7 QUESTIONS BY MR. DOVEL: 8 Q. If there were a true 9 association between acetaminophen and ADHD, 10 would you agree that women should be told to 11 limit acetaminophen use?</p> <p>12 MS. BROWN: I object to the 13 form of the question.</p> <p>14 THE WITNESS: So when you say 15 "true association," do you mean that 16 acetaminophen use was known to be 17 causal?</p> <p>18 QUESTIONS BY MR. DOVEL: 19 Q. I'm using true association the 20 way you did in your 2017 LinkedIn post when 21 you said this appears to be a true 22 association.</p> <p>23 MS. BROWN: Objection to the 24 form. 25 THE WITNESS: True association</p> | <p>1 "no" before you gave that objection? 2 That's completely improper. Do not 3 give him his answers.</p> <p>4 MS. BROWN: I'm not giving 5 anybody any answers.</p> <p>6 MR. DOVEL: Why did you say the 7 word "no"?</p> <p>8 MS. BROWN: Because the 9 question is improper. No, the form of 10 your question is not proper. I 11 object. No, that is not an 12 appropriate question. I object.</p> <p>13 I am not giving anyone any 14 answer.</p> <p>15 MR. DOVEL: Limit it to 16 "objection to form."</p> <p>17 MS. BROWN: I did, sir. I 18 object to the form of your improper 19 question.</p> <p>20 THE WITNESS: Could you repeat 21 your question?</p> <p>22 QUESTIONS BY MR. DOVEL: 23 Q. Sure. 24 You write that, "Many of the 25 environmental causes of ADHD are exposures</p> |

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| <p>1 during fetal development," and say "as a 2 result, improved care for pregnant women is 3 essential." 4 How do we provide -- provide 5 improved care for pregnant women with regard 6 to these environmental exposures during fetal 7 development? 8 MS. BROWN: Object to the form 9 of the question. 10 THE WITNESS: We didn't comment 11 on that because of the -- this -- the 12 team that's writing this are a group 13 of psychiatrists and psychologists. 14 It's outside of our expertise to 15 discuss the details of prenatal care. 16 The -- as I said, the goal of 17 this paper was to talk about -- well, 18 one of the goals of this paper is to 19 talk about -- well, structural 20 disparities, meaning health care 21 disparities. 22 And we were -- one of the 23 concerns is that in -- that women 24 living in poverty aren't getting 25 sufficient prenatal care.</p> | <p>1 about providing better prenatal care 2 to pregnant women, especially those 3 living in poverty. 4 QUESTIONS BY MR. DOVEL: 5 Q. It's not about providing in 6 general better prenatal care. It's because 7 many of the environmental causes are 8 exposures during the fetal development, true? 9 MS. BROWN: Object to the form 10 of the question. 11 THE WITNESS: So let me unpack 12 it for you. 13 So given all of these -- we'll 14 call them exposure associations that 15 we have from different exposures that 16 occur during the fetal period, and 17 also given what we talked about about 18 fetal brain development and so forth, 19 many scientists have hypothesized that 20 this window time during pregnancy 21 could be a period of time when 22 environmental causes, once they're 23 discovered, would impact fetal brain 24 and increase the risk for ADHD. 25 And so all we know is that we</p> |
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| <p>1 However, we clearly are not -- 2 we make no advice here about 3 acetaminophen use. We don't say it's 4 causal. We don't say -- we're not 5 telling women what to do regarding 6 acetaminophen use at all. 7 QUESTIONS BY MR. DOVEL: 8 Q. Would one potential 9 intervention be to warn pregnant women to 10 avoid these exposures? 11 MS. BROWN: I object to the 12 form of the question. 13 THE WITNESS: At this stage, it 14 wouldn't be, because none of these -- 15 none of these exposures are documented 16 to be causal. 17 QUESTIONS BY MR. DOVEL: 18 Q. Okay. Because none of them are 19 documented to be causal, why is it important 20 then to provide pregnant women improved care 21 with regard to these exposures? 22 MS. BROWN: Objection to the 23 form. 24 THE WITNESS: Again, I -- I'll 25 say again that the statement is simply</p> | <p>1 have this hypothesis that this pattern 2 of associations that are the -- if you 3 will, it's kind of the very beginning 4 of understanding causality. 5 We have a pattern of 6 associations from these studies -- are 7 also pointing in that direction, but, 8 again, not at all convincing about 9 causality. 10 So this -- all we're saying is 11 that this period of time seems to be 12 important, and that means that we 13 think that prenatal care should be 14 improved. 15 And we focused on poverty 16 because of course these women are the 17 ones that are getting poor prenatal 18 care. 19 That's also -- well, that's 20 fine. That's enough. 21 QUESTIONS BY MR. DOVEL: 22 Q. According to the authors of the 23 consensus statement on ADHD, there's strong 24 evidence supporting the association between 25 acetaminophen use and -- among pregnant women</p> |

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| <p>1 and then ADHD in their children, right?</p> <p>2 MS. BROWN: Objection to the</p> <p>3 form of the question.</p> <p>4 THE WITNESS: Yeah. The</p> <p>5 consensus statement is reporting what</p> <p>6 we've said before, is that the --</p> <p>7 there is a statistically significant</p> <p>8 association that's been reported, and</p> <p>9 we discuss a number of different</p> <p>10 studies that have reported that</p> <p>11 statistically significant association.</p> <p>12 That's -- I mean, they're</p> <p>13 listed. That's exactly what -- that's</p> <p>14 all we're saying here.</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. There's strong evidence to</p> <p>17 support the association between</p> <p>18 acetaminophen and ADHD?</p> <p>19 A. Where -- I --</p> <p>20 MS. BROWN: Objection to the</p> <p>21 form.</p> <p>22 THE WITNESS: Where are you</p> <p>23 reading that?</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. Let's take a look at the</p> | <p>1 that, yes.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. The authors of the consensus</p> <p>4 statement, "curated findings with a strong</p> <p>5 evidence base."</p> <p>6 A. Strong evidence base as we</p> <p>7 defined in the methods.</p> <p>8 Q. One of those findings with the</p> <p>9 strong evidence base was that acetaminophen</p> <p>10 use during pregnancy was associated with</p> <p>11 ADHD?</p> <p>12 A. Correct. There's an important</p> <p>13 distinction here is that when we say the</p> <p>14 evidence base is strong, we're saying that</p> <p>15 it's based on I think -- let me just see what</p> <p>16 we exactly say, so I don't get it -- I get it</p> <p>17 right. Come on. Where's that? It's in the</p> <p>18 methods section here.</p> <p>19 Essentially we were looking for</p> <p>20 large cohort studies -- okay. So the</p> <p>21 sentence -- the paragraph, I guess it's 792,</p> <p>22 left column towards the bottom, just before</p> <p>23 the yellow highlighting, "apart from</p> <p>24 statements about the history of ADHD and its</p> <p>25 diagnostic criteria, we required each</p> |
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| <p>1 abstract of the consensus statement,</p> <p>2 Exhibit 781.</p> <p>3 The abstract appears on</p> <p>4 page 791 at the very bottom.</p> <p>5 This is Exhibit 781.</p> <p>6 In the abstract, you and the</p> <p>7 other authors write, "To challenge</p> <p>8 misconceptions, we curated findings with</p> <p>9 strong evidence base."</p> <p>10 A. Oh, where are we now?</p> <p>11 Q. 791, bottom.</p> <p>12 A. Bottom. I'm sorry, I'm on the</p> <p>13 wrong page? 792. Sorry.</p> <p>14 MS. BROWN: It's all right.</p> <p>15 THE WITNESS: Sorry.</p> <p>16 QUESTIONS BY MR. DOVEL:</p> <p>17 Q. 792 would be the page right</p> <p>18 before 791.</p> <p>19 A. Yeah.</p> <p>20 MS. BROWN: Hold on. We're</p> <p>21 getting him there.</p> <p>22 THE WITNESS: I'm on the wrong</p> <p>23 page. Okay.</p> <p>24 MS. BROWN: Take your time.</p> <p>25 THE WITNESS: Okay. I see</p> | <p>1 evidence-based statement to be supported by</p> <p>2 meta-analyses or by large registry studies</p> <p>3 with more than 2,000 participants. We</p> <p>4 require -- we required meta-analysis support</p> <p>5 data from five or more studies or 2,000 or</p> <p>6 more participants."</p> <p>7 So that's the definition of</p> <p>8 strong evidence base. It doesn't mean that a</p> <p>9 finding from a particular study is strong in</p> <p>10 terms of the -- for example, its effect size</p> <p>11 or in any other way. That's -- that's the</p> <p>12 only thing that that means.</p> <p>13 Q. If when you examined the</p> <p>14 evidence on a topic and found that it was</p> <p>15 insufficient to allow a firm conclusion, did</p> <p>16 you then publish that conclusion?</p> <p>17 A. It shouldn't -- it doesn't --</p> <p>18 it should not appear in one of the 208 items</p> <p>19 in evidence in here. It's --</p> <p>20 Q. If exhibit -- withdrawn.</p> <p>21 In the consensus statement, the</p> <p>22 statements regarding acetaminophen and ADHD</p> <p>23 were statements that based upon reading this</p> <p>24 study you concluded the evidence was</p> <p>25 sufficient to allow firm conclusion?</p> |

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| <p>1 A. In the sense that the -- in the 2 case of the acetaminophen studies, that a 3 certain odds ratio was reported as 4 statistical -- statistically significant and 5 that we were not -- that that fact was a 6 fuel -- firm conclusion from that study. 7 It doesn't say that it may -- 8 that it may -- that it was confounded or -- 9 it was or was not confounded. It certainly 10 doesn't say it was causal. It just says that 11 that association is a firm conclusion. 12 We're talking now about the 13 report of association there. We're not 14 talking about whether it was confounded or 15 not. 16 MR. DOVEL: Let's go off the 17 record. 18 VIDEOGRAPHER: The time right 19 now is 4:30 p.m. We're off the 20 record. 21 (Off the record at 4:30 p.m.) 22 VIDEOGRAPHER: The time right 23 now is 4:47 p.m. We are back on the 24 record. 25 (Faraone Exhibit 794 and 711</p> | <p>1 A. All right. Let me just go down 2 the list here. 3 Devices would be -- let's see. 4 Akili Interactive, Atentiv, CogCubed. 5 Enzymotec is the -- they were trying to 6 develop a Vayarin, which is kind of a 7 supplement -- nutritional supplement. It 8 didn't work. 9 Many of these are no longer 10 active too, but I can tell you that if you 11 want to know. 12 Let's see. Well, Genomind is a 13 company that does pharmacogenetics and other 14 genetic work, in not just ADHD, but in lots 15 of spaces. 16 Let's see. Ondosis is a 17 device. 18 Okay. And then on the other 19 side, via -- you'll, VAYA is -- actually VAYA 20 and Enzymotec are the same. I forget one -- 21 the relationship with them is basically the 22 same. 23 Q. Is VAYA a device manufacturer? 24 A. VAYA -- VAYA is, like 25 Enzymotec, it's a nutritional supplement.</p> |
| Page 422 | Page 424 |
| <p>1 marked for identification.) 2 QUESTIONS BY MR. DOVEL: 3 Q. I'm going to mark as 4 Exhibit 794 a diagram that I drew regarding 5 genetics, acetaminophen and ADHD. 6 MS. BROWN: Objection to the 7 exhibit. 8 QUESTIONS BY MR. DOVEL: 9 Q. I'm going to mark as 10 Exhibit 711 a list of pharmacy companies 11 entitled "Dr. Faraone cash from pharma." 12 MS. BROWN: I object to 711. 13 QUESTIONS BY MR. DOVEL: 14 Q. Sir, I've identified here a 15 number of pharmaceutical companies on the 16 first page and three more on the second page. 17 Do you see that? 18 A. I do, yes. These are not all 19 pharmaceutical companies. Some of these make 20 devices for ADHD. Other make -- one of them 21 is a bionutritional supplement for ADHD. 22 Let's see. 23 Devices -- yeah. So most of 24 them are pharmaceutical companies, but -- 25 Q. Which ones are devices?</p> | <p>1 Vayarin was the -- it's no longer in 2 development for ADHD. But it was -- failed 3 clinical trial. 4 Q. All right. Thank you for 5 clarifying that. 6 Now, from each of the 7 pharmaceutical companies listed here, have 8 you taken money? 9 MS. BROWN: Objection to the 10 form. 11 THE WITNESS: Let me just 12 double-check for sure. So I have -- 13 yeah, I have received consulting fees 14 from all the companies listed here. 15 QUESTIONS BY MR. DOVEL: 16 Q. From Janssen, the J&J 17 subsidiary, were you on their advisory board? 18 A. Well, I have to clarify a point 19 about advisory boards in this area. 20 Frequently -- sometimes a 21 company -- like Genomind, for example, has a 22 more or less permanent advisory board for the 23 company. And I am on their advisory board in 24 that capacity. 25 The other -- the other</p> |

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| <p>1 companies will periodically convene an 2 advisory board. It's not a permanent board. 3 It's convened for a special purpose, and it's 4 called an advisory board. 5 And the other ones are -- when 6 it says -- when an advisory board is listed, 7 it means that I was invited to an advisory 8 board to advise them on a specific topic, for 9 example, a clinical trial, and then once -- 10 that might be one meeting, it could be a 11 series of meetings, but once that's over, 12 then the advisory board ends. 13 So the only one that is -- 14 that -- actually, I take it back. I think 15 Aard -- I can't even say it. Aardvark 16 Therapeutics is also more of a -- an advisory 17 board in the sense of standing advisory 18 board. 19 Q. Now, with Janssen, did you 20 participate in their speakers bureau? 21 A. I believe I gave -- this is -- 22 I'm -- this is hard to remember. This goes 23 back to the 1990s, early -- maybe early 24 2000s. 25 So -- and I -- well, what I</p> | <p>1 recall when I was working with McNeil doing 2 consulting on Concerta that -- because we 3 would do -- there's two kinds of talks one 4 gives about -- when educating people. 5 There's continuing education talks, which 6 are -- what are they called there? Those are 7 talks that are independent talks developed by 8 investigators that have fair balance, they're 9 about multiple products and/or not about 10 products at all. 11 And then there are sometimes 12 commercial talks, which are meant to educate 13 doctors about a company's product. 14 So back in -- when I was first 15 starting as -- I was young. I didn't quite 16 get the distinction there, and I believe I 17 did participate in one or two, I'm not sure 18 how many, talks with McNeil. And then I 19 stopped doing that once I realized that they 20 were -- you know, that they were talks that 21 were about the drug Concerta, but I wasn't 22 talking about other drugs as well. 23 And so I may have given one or 24 two talks of that sort, but otherwise, I've 25 not been on that kind of speakers bureau. I</p> |
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| <p>1 was -- to clarify this, McNeil developed a 2 drug called Concerta for ADHD, and I 3 essentially advised -- was advising people at 4 McNeil. 5 McNeil, I think, was -- I think 6 was acquired by Janssen, which was acquired 7 by J&J. I don't understand it completely, 8 but I was dealing with people from McNeil. 9 And I definitely participated in advisory 10 boards. I was a consultant. I don't 11 believe -- I don't believe I was on the 12 speakers bureau for them. 13 Q. What is a speakers bureau? 14 A. Well, a speakers bureau refers 15 to speakers who speak on -- well, usually -- 16 it's not always consistent, but usually it 17 means people who speak on -- okay. Let me 18 back up here. 19 It is people who speak on 20 behalf of a company's product, they give 21 talks about the company's product as opposed 22 to other types of speaking one might do. 23 And I don't -- I'm not sure 24 why I listed that there. It's possible -- 25 there was a time when I was doing the -- I do</p> | <p>1 have engaged in continuing education talks, 2 but not in -- of those kinds of -- well, 3 we'll call it -- they're sometimes called -- 4 well, speakers bureau talks, talks that are 5 limited to one product. 6 Q. Have you also been paid by 7 Ely Lilly? 8 A. I was a consultant with 9 Ely Lilly regarding atomoxetine. 10 Q. Novartis, Pfizer and 11 Shire-Takeda as well? 12 A. Correct. 13 Q. How much money did you receive 14 altogether from Janssen and McNeil? 15 A. This was a long time ago. I 16 don't have a number for that. I'm... 17 Q. In a typical year, or let's 18 take over the last ten years, in a typical 19 year, do you receive money from more than one 20 pharmaceutical company? 21 A. Did you say over the last five 22 years? 23 Q. Last five -- 24 A. Okay. Whatever. 25 And more than -- yes. Yes.</p> |

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| <p>1 Yes.</p> <p>2 Q. In a typical year, how many</p> <p>3 pharmaceutical companies pay you money?</p> <p>4 A. That's listed on my -- you can</p> <p>5 find it at my website. I list the companies</p> <p>6 that I've worked with over the past, I</p> <p>7 believe, two years.</p> <p>8 Q. Yeah. I need an answer to my</p> <p>9 question, though.</p> <p>10 A. I would say currently it's</p> <p>11 about 12. It's not an exact number, but it's</p> <p>12 around 12. Including device companies and so</p> <p>13 forth, yes.</p> <p>14 Q. Is that -- is the money you get</p> <p>15 from pharmaceutical companies each year a</p> <p>16 substantial portion of your income?</p> <p>17 A. I don't have an exact figure.</p> <p>18 It's not a large percentage of my income, but</p> <p>19 it's substantial in the sense that it's -- I</p> <p>20 would say it's hard to know -- I'm not sure</p> <p>21 what you mean by "substantial." Maybe -- you</p> <p>22 mean like 10 percent, 20 percent?</p> <p>23 Q. Does it total tens of thousands</p> <p>24 of dollars each year?</p> <p>25 MS. BROWN: Counsel, I think we</p> | <p>1 direct him not to answer any of these</p> <p>2 questions until we can sort that out</p> <p>3 because I understand these are</p> <p>4 violating an agreement.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. In this case, you've -- at</p> <p>7 least up through --</p> <p>8 A. I just -- I want to just --</p> <p>9 THE WITNESS: Well, I'm not</p> <p>10 supposed to answer?</p> <p>11 MS. BROWN: So don't go back on</p> <p>12 that until we can work this out.</p> <p>13 THE WITNESS: Okay.</p> <p>14 MS. BROWN: And I'm happy to go</p> <p>15 off the record, if you want, Counsel.</p> <p>16 I just understand there's an</p> <p>17 agreement, and these questions are in</p> <p>18 violation.</p> <p>19 THE WITNESS: Okay. I just</p> <p>20 want to say I'm just -- I'm working</p> <p>21 off of memory here, so it's hard to,</p> <p>22 you know -- you said tens of</p> <p>23 thousands. It's certainly more than</p> <p>24 10,000. I don't have a number that I</p> <p>25 can -- you know, that I can give you.</p> |
| Page 430 | Page 432 |
| <p>1 have an agreement that these questions</p> <p>2 are not appropriate.</p> <p>3 MR. DOVEL: We don't.</p> <p>4 MS. BROWN: Did you just ask</p> <p>5 about the portion of his income?</p> <p>6 MR. DOVEL: No. I just need an</p> <p>7 answer to my question.</p> <p>8 MS. BROWN: Okay. I'm going to</p> <p>9 object on the record, and I'll follow</p> <p>10 up. I think we have an agreement, and</p> <p>11 I think you're violating it.</p> <p>12 THE WITNESS: Yeah.</p> <p>13 I can answer?</p> <p>14 MS. BROWN: Go ahead, for now.</p> <p>15 THE WITNESS: Tens of thousands</p> <p>16 is accurate. It's --</p> <p>17 MS. BROWN: Okay. Hold on a</p> <p>18 second.</p> <p>19 Counsel, I understand there is</p> <p>20 an agreement, and these questions</p> <p>21 violate it. So --</p> <p>22 MR. DOVEL: The question I</p> <p>23 asked did not violate it. I know what</p> <p>24 you're referring to. Let me proceed.</p> <p>25 MS. BROWN: Okay. I'm going to</p> | <p>1 That's -- I don't want to -- someone</p> <p>2 to come back later and say, "You</p> <p>3 weren't accurate about that."</p> <p>4 QUESTIONS BY MR. DOVEL:</p> <p>5 Q. I received copies of your</p> <p>6 invoices that you billed in this case.</p> <p>7 A. Yes.</p> <p>8 Q. To date, up through the end of</p> <p>9 August, they totaled more than \$200,000.</p> <p>10 Does that sound right?</p> <p>11 A. That sounds exactly right. I</p> <p>12 think it's about 210, something like that,</p> <p>13 215.</p> <p>14 Q. For your time today, as well as</p> <p>15 your time in preparing for trial and</p> <p>16 testifying at trial, do you anticipate</p> <p>17 altogether you'll be receiving more than a</p> <p>18 quarter of a million dollars for your work in</p> <p>19 this case?</p> <p>20 A. I haven't computed that. I</p> <p>21 don't know -- this is the first time I've</p> <p>22 done this, so I have no idea what happens</p> <p>23 after this. Whether they'll need me in the</p> <p>24 future or not need me, I just don't know.</p> <p>25 I'm new at this time.</p> |

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| <p>1 (Faraone Exhibit 722 marked for 2 identification.) 3 QUESTIONS BY MR. DOVEL: 4 Q. I'll mark as Exhibit 772 {sic} 5 the Faraone report on causes of ADHD. 6 MS. BROWN: I object to 7 -- 7 did you say 772? 8 MR. DOVEL: 722. 9 MS. BROWN: Oh, okay. The 10 realtime said 772. 11 I object to 722. 12 QUESTIONS BY MR. DOVEL: 13 Q. Now, the first quote here -- 14 all these quotes are from your report. The 15 first one is from your conclusion, 16 paragraph 6, where you say "Genetics are 17 considered the predominant cause of ADHD, and 18 when studies of proposed environmental risk 19 factors have used study designs that account 20 for the role of familial/genetic liability, 21 the elevated risk disappeared." 22 You make other statements along 23 those lines, and I've quoted some of those 24 here. 25 In your report, for example, at</p> | <p>1 articles, from the consensus statement on the 2 causes of ADHD. 3 For example, the first one, 4 "Most cases of ADHD are caused by the 5 combined effects of many genetic and 6 environmental risks." 7 Do you see that? 8 A. I do see that. 9 Q. You did not report in your 10 report anywhere, it didn't state anywhere in 11 your report, that most of the cases are 12 caused by the combined effects of genetic and 13 environmental risks, right? 14 A. That -- that statement, I would 15 have to read the report again. I don't 16 recall that it's in -- that statement is in 17 the report. 18 Q. Well, you understood that your 19 assignment for Johnson & Johnson on their 20 behalf was to magnify and exaggerate the 21 impact of genetic factors and minimize the 22 impact of environmental factors? 23 A. Well, no, I completely disagree 24 with that statement. 25 Q. You understand that</p> |
| Page 434 | Page 436 |
| <p>1 paragraph 58, you say, "Most cases of ADHD 2 are caused by relatively common genetic 3 variants." 4 Do you see that? 5 A. I see that, yes. 6 Q. That's really minimizing the 7 role of the environmental effects, right? 8 MS. BROWN: Objection to the 9 form of that question. 10 THE WITNESS: Well, given that 11 heritability is 76 percent, it's -- it 12 seems reasonable -- this is a -- it 13 seems reasonable to state that most 14 cases are going to have these common 15 genetic variants causes. 16 (Faraone Exhibit 723 marked for 17 identification.) 18 QUESTIONS BY MR. DOVEL: 19 Q. I mark -- I'm going to mark as 20 Exhibit 723 Science on causes of ADHD. 21 MS. BROWN: I object to 723. 22 QUESTIONS BY MR. DOVEL: 23 Q. Now, sir, these are quotes from 24 the documents we've looked at today from the 25 ADHD Evidence Project, from your various</p> | <p>1 acetaminophen is an environmental factor? 2 A. I completely disagree -- I'm 3 sorry. You have just said that I have an 4 assignment from Johnson & Johnson to 5 exaggerate? 6 No one has ever told me that my 7 assignment was to exaggerate. My -- I was 8 told that my assignment was to use my 9 expertise in the area of ADHD to prepare the 10 report that we have here today. 11 Nobody has ever told me to 12 exaggerate anything. I have never spoken to 13 anybody at Johnson & Johnson about this 14 litigation, so the premise of that question 15 is just 100 percent wrong. 16 Q. Well -- 17 MS. BROWN: Hold on. 18 QUESTIONS BY MR. DOVEL: 19 Q. -- any communications you've 20 had have been with the lawyers for Johnson & 21 Johnson, right? 22 MS. BROWN: I would like a 23 belated objection to the exaggeration 24 question on form, please, but, Doctor. 25 THE WITNESS: Repeat that,</p> |

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| <p>1 please.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Yeah.</p> <p>4 Your communications have been</p> <p>5 with the lawyers for Johnson & Johnson?</p> <p>6 A. That's correct, yes. And they</p> <p>7 did not ask me -- no one has ever asked me to</p> <p>8 exaggerate anything.</p> <p>9 Q. You understand, sir, that</p> <p>10 acetaminophen is an environmental cause of</p> <p>11 ADHD; it's purported to be, right, in this</p> <p>12 case?</p> <p>13 MS. BROWN: I object to the</p> <p>14 form of the question.</p> <p>15 THE WITNESS: Well, I disagree</p> <p>16 with the statement that it's an</p> <p>17 environmental cause --</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. You understand --</p> <p>20 A. -- to ADHD.</p> <p>21 Q. -- that's the allegation, that</p> <p>22 it's an environmental cause, right?</p> <p>23 A. I understand that that's what</p> <p>24 the plaintiffs are stating.</p> <p>25 Q. And you understand that it</p> | <p>1 That's -- it has nothing to do with --</p> <p>2 it does not in any way help any -- I</p> <p>3 mean, the only thing that would help</p> <p>4 the defense attorneys if I said it's</p> <p>5 100 percent genetic and no</p> <p>6 environmental -- no environment --</p> <p>7 none of these environmental risks at</p> <p>8 all are relevant.</p> <p>9 So I think you're wrong about</p> <p>10 that. There's plenty of room --</p> <p>11 there's plenty of room for the</p> <p>12 environment in the way I presented the</p> <p>13 data in terms of the heritability of</p> <p>14 ADHD.</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. In your --</p> <p>17 A. There's no question about that.</p> <p>18 Q. In your writings in your</p> <p>19 published peer-reviewed statements about the</p> <p>20 causes of ADHD, in your writings on your ADHD</p> <p>21 Evidence website, in your writings in the</p> <p>22 consensus statement, you always consistently</p> <p>23 state that most cases of ADHD are caused by</p> <p>24 the combined effects of genes and</p> <p>25 environment, right?</p> |
| Page 438 | Page 440 |
| <p>1 benefits Johnson & Johnson to suggest that</p> <p>2 ADHD and autism are caused almost all by</p> <p>3 genetics and with very little environmental</p> <p>4 effect, right?</p> <p>5 MS. BROWN: I object to the</p> <p>6 form of the question.</p> <p>7 THE WITNESS: I disagree --</p> <p>8 MS. BROWN: I object to the</p> <p>9 form.</p> <p>10 THE WITNESS: I disagree with</p> <p>11 that. I don't know -- I'm not in this</p> <p>12 position to ben -- to state -- I think</p> <p>13 what you're stating is that when I --</p> <p>14 when I -- when I provide you with the</p> <p>15 fact that ADHD is 76 percent</p> <p>16 heritability and 25 percent</p> <p>17 environment, and that the</p> <p>18 environmental contribution is less,</p> <p>19 that somehow that minimizes the role</p> <p>20 of the environment.</p> <p>21 There's still -- in everything</p> <p>22 I've said to you today, I have said</p> <p>23 there is a role for the environment.</p> <p>24 And a role for the environment</p> <p>25 includes any kinds of exposures.</p> | <p>1 A. Well, the sentence is, of</p> <p>2 course, taken out of context. It doesn't</p> <p>3 change the heritability that most of that is</p> <p>4 genetic and some of it is environmental.</p> <p>5 And this is, of course --</p> <p>6 remember, this is -- these are -- this is</p> <p>7 a --</p> <p>8 Q. I just need an answer to my</p> <p>9 question.</p> <p>10 MS. BROWN: No. No. Please</p> <p>11 let him finish.</p> <p>12 THE WITNESS: No, I am</p> <p>13 answering the question because I think</p> <p>14 it's important that one understands</p> <p>15 that this is my working hypothesis</p> <p>16 that we -- that genes and environment</p> <p>17 are combining to cause many cases of</p> <p>18 ADHD. We still need the research to</p> <p>19 be done to tell us exactly what that</p> <p>20 mix is, but I think this is a</p> <p>21 reasonable hypothesis.</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. Is it true that in your</p> <p>24 statements, outside of your report, you</p> <p>25 consistently state that most cases of ADHD</p> |

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| <p style="text-align: right;">Page 441</p> <p>1 are caused by the combined effects of genes 2 and environmental risks? 3 MS. BROWN: Object to the form 4 of the question. 5 THE WITNESS: Because 6 outside -- because -- in my scientific 7 writings, I frequently state 8 hypotheses. The point behind this 9 report that I have written for this 10 litigation is to answer the question 11 about -- very specific question about 12 causality. It's not to state some of 13 my hypotheses about what I think might 14 ultimately be discovered down -- in 15 the future. 16 QUESTIONS BY MR. DOVEL: 17 Q. Well, you said hypotheses. 18 Isn't it your firm conclusion that for most 19 people with ADHD, many genetic and 20 environmental risk factors are accumulated to 21 cause the disorder? 22 A. I -- when you say "firm 23 conclusion," you're referring to the 24 International Consensus Statement? 25 Q. Yes.</p> | <p style="text-align: right;">Page 443</p> <p>1 different. 2 I see where you're -- you've 3 highlighted these. It's in the 4 discussion. It's not a numbered item. 5 QUESTIONS BY MR. DOVEL: 6 Q. And in your paper that you 7 wrote with Khoury, you stated that "ADHD is 8 most commonly caused by the cumulative 9 effects of genes and environmental risks." 10 Right? 11 A. You have that written here, and 12 if you've taken -- if that's an accurate -- 13 that's -- you know, I don't have -- I don't 14 have the article in front of me. Do you want 15 me to -- should I -- can we check the 16 article, if you want me to state that that's 17 accurate? 18 Q. I want you to assume that you 19 wrote that. 20 MS. BROWN: Well, I object -- 21 QUESTIONS BY MR. DOVEL: 22 Q. My question, sir, is, why 23 didn't you include any of these quotes in 24 your report to the Court -- 25 A. Because --</p> |
| <p style="text-align: right;">Page 442</p> <p>1 A. I don't believe that's one of 2 the 208 inclusions. Which number is that? I 3 don't -- 4 Q. Page 806. I'm quoting from 5 there. 6 A. Page 806. 7 Q. I've got it written here. We 8 don't need to look it up right now. 9 Let me just back up, sir. 10 A. Well, the number -- because 11 I -- 12 MS. BROWN: Hold on. Hold on. 13 Hold on. 14 If there's a pending question, 15 let's let him answer it. 16 MR. DOVEL: Well, I'm 17 withdrawing it. 18 THE WITNESS: Because it's not 19 one of the 208 evidence-based 20 conclusions. It's something that is 21 put in the discussion section when 22 there we talk about hypotheses and 23 other things. It's not -- it's not 24 one of the firm 208 evidence-based 25 conclusions. That's a -- those are</p> | <p style="text-align: right;">Page 444</p> <p>1 Q. -- and the jury regarding the 2 causes of ADHD? 3 MS. BROWN: Hold on. 4 I object to the form of the 5 question. 6 Go ahead. 7 And here's the article if you 8 need to look at it. 9 THE WITNESS: Okay. Okay. 10 Because when I am writing this 11 report, talking about -- specifically 12 about the data and the facts. The 13 best fact we have about the relative 14 contribution of genes and environment 15 comes from the heritability 16 statistics. It doesn't come from my 17 hypotheses about what is likely to be 18 the case in the future when we 19 understand how environmental risks and 20 genetic causes combine with one 21 another. 22 That's the -- that's why 23 it's -- the best way to do it is 24 regarding the heritability statistic. 25</p> |

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| <p style="text-align: right;">Page 445</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. You told the Court that various</p> <p>3 organizations agreed with your conclusion</p> <p>4 that's in your report, that acetaminophen is</p> <p>5 not causal, has no association with causing</p> <p>6 ADHD, right?</p> <p>7 A. Yes, there's a section about</p> <p>8 that.</p> <p>9 Q. You did not include the fact</p> <p>10 that the World Federation of ADHD has</p> <p>11 concluded that there's firm evidence showing</p> <p>12 an association between acetaminophen exposure</p> <p>13 and ADHD, right?</p> <p>14 MS. BROWN: Object -- objection</p> <p>15 to the form.</p> <p>16 THE WITNESS: The World</p> <p>17 Federation has no expertise in the</p> <p>18 area of -- in the area of women's</p> <p>19 health, OB/GYN and fetal and maternal</p> <p>20 medicine and so forth.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Okay. But they do have</p> <p>23 expertise --</p> <p>24 MS. BROWN: You cut him off</p> <p>25 again.</p> | <p style="text-align: right;">Page 447</p> <p>1 question.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. Okay. Are you aware of any</p> <p>4 group that has more information about the</p> <p>5 causes and risks of ADHD than the 77 authors</p> <p>6 and 300 folks who signed on to the consensus</p> <p>7 statement?</p> <p>8 MS. BROWN: I object to the</p> <p>9 form of the question.</p> <p>10 THE WITNESS: Let me just read</p> <p>11 the question again.</p> <p>12 I can't say I know of any</p> <p>13 group. There may be some individuals</p> <p>14 who have a fair -- a good deal of</p> <p>15 knowledge in this, but not any</p> <p>16 specific group.</p> <p>17 QUESTIONS BY MR. DOVEL:</p> <p>18 Q. Why is it that you elected not</p> <p>19 to tell the Court about the consensus</p> <p>20 statement conclusion regarding acetaminophen</p> <p>21 exposure and ADHD?</p> <p>22 MS. BROWN: I object to the</p> <p>23 form of the question.</p> <p>24 THE WITNESS: Because -- well,</p> <p>25 first of all, I didn't specifically</p> |
| <p style="text-align: right;">Page 446</p> <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. -- in causes of ADHD, right?</p> <p>3 MS. BROWN: Counsel, you cut</p> <p>4 him off again. Please let him finish.</p> <p>5 THE WITNESS: And what the --</p> <p>6 the consensus statement simply is</p> <p>7 not -- a consensus statement is not</p> <p>8 drawing any conclusions about -- does</p> <p>9 not draw conclusions -- well, what the</p> <p>10 consensus statement says is that</p> <p>11 acetaminophen is a correlate of ADHD</p> <p>12 and has not been documented to be a</p> <p>13 cause of ADHD.</p> <p>14 That's what it says.</p> <p>15 QUESTIONS BY MR. DOVEL:</p> <p>16 Q. The con -- folks who wrote the</p> <p>17 consensus statement collectively have more</p> <p>18 information about the causes and risks of</p> <p>19 ADHD than do the doctors at ACOG, right?</p> <p>20 MS. BROWN: I object to the</p> <p>21 form of that question.</p> <p>22 THE WITNESS: I don't know what</p> <p>23 the doctors at ACOG have looked at</p> <p>24 when they did their deliberations.</p> <p>25 I don't have an answer to that</p> | <p style="text-align: right;">Page 448</p> <p>1 elect not to say anything. I</p> <p>2 didn't -- I didn't, for example, say</p> <p>3 Ah, I should make sure not to include</p> <p>4 this in the report.</p> <p>5 Part of the report was going to</p> <p>6 be reviewing the evidence from the</p> <p>7 epidemiologic studies. In fact, I</p> <p>8 have a bunch of pages of the report</p> <p>9 which do that and which do that in a</p> <p>10 very specific way where I -- kind of</p> <p>11 transparently reporting which articles</p> <p>12 I have selected, why I have selected</p> <p>13 them and so forth.</p> <p>14 That provides much more</p> <p>15 information about my thought processes</p> <p>16 going into the Bradford Hill criteria</p> <p>17 and the World Federation report which</p> <p>18 is simply listing -- providing a list</p> <p>19 of articles that we -- that met our</p> <p>20 criteria for being in the report.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. Sir, it doesn't just provide a</p> <p>23 list of articles; it has specific statements</p> <p>24 that are identified as evidence-based</p> <p>25 statements, true?</p> |

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| <p>1 A. Correct. Correct. It provides 2 a list of evidence-based statements about 3 these articles. 4 And as I -- 5 Q. One of those evidence-based -- 6 MS. BROWN: Wait, he's not 7 done. Please. Please. 8 THE WITNESS: As I said, if 9 we -- if you look at the report, which 10 I'm sure you have, there's a section 11 that is reviewing -- that reviews the 12 epidemiologic literature, reviews the 13 association studies and does a deep 14 dive into my analyses of those studies 15 as regards what I -- what I view as 16 some of the key methodologic features 17 of those studies such as confounding, 18 biases, the probable multiplicity, 19 none of which is addressed in the 20 consensus statement. 21 I also report the odds ratios. 22 I also report -- well, I'm not 23 hiding -- I'm not hiding the fact that 24 there have been many studies that have 25 reported relative risks of the</p> | <p>1 with acetaminophen, right? 2 A. Depends what you mean by 3 "many," but I have written -- made some -- I 4 have written some statements about that, yes. 5 Q. Okay. In your report, did you 6 identify any of those statements that you 7 previously made about the relationship of 8 acetaminophen and ADHD? 9 MS. BROWN: Objection to the 10 form. 11 THE WITNESS: None -- I -- 12 well, no. There's no prior report 13 where I did a deep dive into the 14 literature so where I could completely 15 and fully understand the nature of 16 those associations. 17 I didn't -- I don't -- I 18 didn't -- I didn't deem that they 19 were -- I didn't think that they were 20 relevant to the report because the 21 report essentially is reviewing those 22 associations in detail following 23 the methods that I described and how 24 I -- how I reviewed those studies 25 and --</p> |
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| <p>1 magnitude that are reported there. 2 So there's -- nothing's being 3 hidden. The evidence is there for the 4 Court to see. 5 QUESTIONS BY MR. DOVEL: 6 Q. You commented on the Bauer 7 consensus statement, right? 8 A. I believe that's in this 9 report. I have to -- I would have to look at 10 it again to be sure that's correct. 11 I'm not actually sure that I 12 said a lot about that, but what paragraph is 13 that in? 14 Q. One of the things that's 15 relevant to this case is whether or not 16 acetaminophen is truly associated with ADHD. 17 Right? 18 MS. BROWN: I object to the 19 form of the question. 20 THE WITNESS: Absolute -- yes. 21 The association statistic is a -- is 22 an important part of this question. 23 QUESTIONS BY MR. DOVEL: 24 Q. Before this case, you wrote 25 many statements about the association of ADHD</p> | <p>1 QUESTIONS BY MR. DOVEL: 2 Q. You don't think it's 3 relevant that -- 4 A. As -- 5 MS. BROWN: Please let him 6 finish. 7 THE WITNESS: As opposed to -- 8 as opposed to some of the statements 9 you refer to are done in very brief, 10 informal blog posts where -- that are 11 meant to engage an audience in 12 scientific research by pointing them 13 to articles of interest. 14 They're not deep dives into the 15 literature or anything -- or anything 16 of that sort. And so they're not 17 really appropriate or relevant to a 18 very considered, detailed analysis of 19 the studies that are involved in 20 determining Bradford Hill criteria. 21 In fact, none of those blogs 22 are even addressing Bradford Hill 23 criteria at all. They're only 24 addressing some specific studies that 25 were of interest to me at the time.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. Is your statement -- before you</p> <p>3 signed on to work for Johnson & Johnson's</p> <p>4 lawyer, is your statements about</p> <p>5 acetaminophen and ADHD -- do you think</p> <p>6 they're just completely irrelevant?</p> <p>7 MS. BROWN: Objection to the</p> <p>8 form of the question.</p> <p>9 THE WITNESS: I don't think</p> <p>10 they add anything to my discussion of</p> <p>11 the full -- the -- to the full body of</p> <p>12 literature following a -- the</p> <p>13 methodology that I decided to use to</p> <p>14 review that literature.</p> <p>15 They don't address -- they</p> <p>16 don't address really any of the</p> <p>17 features of the studies that are</p> <p>18 relevant to Bradford Hill criteria.</p> <p>19 So I don't see how they're -- I don't</p> <p>20 see how they're relevant.</p> <p>21 QUESTIONS BY MR. DOVEL:</p> <p>22 Q. When you wrote your article</p> <p>23 in -- published with Khoury in 2022, you were</p> <p>24 certainly aware of the concept of a</p> <p>25 sibling-control study, right?</p> | <p>1 And again, I do that because</p> <p>2 it -- the article came across my -- it came</p> <p>3 to my attention, and I -- the goal of -- the</p> <p>4 goal of these blog posts is to share evidence</p> <p>5 with the people who like to, you know, look</p> <p>6 at my blogs.</p> <p>7 It's not to, you know, do any</p> <p>8 deep dives into any specific article or</p> <p>9 specific topic. It's just to share evidence</p> <p>10 so people can go and draw their own</p> <p>11 conclusions.</p> <p>12 When I want to do a deep dive</p> <p>13 into a topic, I typically will write a paper</p> <p>14 about that topic.</p> <p>15 Q. You agree, sir, that oxidative</p> <p>16 stress can produce epigenetic modifications</p> <p>17 of the genome?</p> <p>18 MS. BROWN: Object to the form</p> <p>19 of the question.</p> <p>20 THE WITNESS: Okay. We're</p> <p>21 changing the subject here.</p> <p>22 I -- again, I'm not an expert</p> <p>23 in epigenetics, but I think -- it's</p> <p>24 been a while since I've looked at that</p> <p>25 literature, so I would want to look at</p> |
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| <p>1 A. I was -- I should have -- I was</p> <p>2 aware of the sibling-control study. I was</p> <p>3 aware of the concept of a sibling-control</p> <p>4 study in 20 -- well, what, 2022?</p> <p>5 Well, it was probably not</p> <p>6 written in 2022, but whatever, in that time</p> <p>7 frame. It was -- I'm not exactly sure when</p> <p>8 it was written because the publication date</p> <p>9 frequently is somewhat delayed from the</p> <p>10 actual writing date.</p> <p>11 I -- it may have been -- it may</p> <p>12 have been -- there's a good chance it was</p> <p>13 written in 2021, so I'm not sure, because</p> <p>14 Gustavson came out in 2021. I may not have</p> <p>15 seen Gustavson when this thing was written.</p> <p>16 Q. You were aware of Brandlistuen,</p> <p>17 which was a sibling-control study, right?</p> <p>18 A. I was, yes. Yes.</p> <p>19 Q. And you relied upon</p> <p>20 Brandlistuen in part of the conclusions that</p> <p>21 you wrote in some of your blog posts and your</p> <p>22 articles, right?</p> <p>23 A. I do mention the Brandlistuen</p> <p>24 study in at least one of the blog posts,</p> <p>25 correct.</p> | <p>1 that again before I said something</p> <p>2 specific about it.</p> <p>3 There are other people who I</p> <p>4 think are addressing this issue.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. Well, in your article with</p> <p>7 Antshel, it's one of the things that you</p> <p>8 wrote, is that oxidative stress can produce</p> <p>9 epigenetic modifications of a genome, right?</p> <p>10 Does that sound familiar?</p> <p>11 A. Can I see the article?</p> <p>12 MS. BROWN: Yep.</p> <p>13 THE WITNESS: Where is it?</p> <p>14 Which one's that?</p> <p>15 MR. DOVEL: 777.</p> <p>16 MS. BROWN: Let's find it.</p> <p>17 THE WITNESS: Okay. Antshel.</p> <p>18 I don't believe I have that</p> <p>19 one. I'm pretty sure we don't.</p> <p>20 QUESTIONS BY MR. DOVEL:</p> <p>21 Q. It looks like this.</p> <p>22 MS. BROWN: I got it. Here.</p> <p>23 Take mine.</p> <p>24 THE WITNESS: Okay. Got it.</p> <p>25 Okay. Yeah. Yeah. Got it, yes.</p> |

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| <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. If we look at page 11 -- oops,</p> <p>3 I'm sorry. Page 1119, paragraph 3.</p> <p>4 A. Okay. All right. I'm there.</p> <p>5 Q. Sentence one you identify,</p> <p>6 "Genetic alterations, such as mutations and</p> <p>7 expression changes of epigenetic genes,</p> <p>8 environmental risk factors, including</p> <p>9 exposure to environmental toxins," and so on,</p> <p>10 "including oxidative stress, all can produce</p> <p>11 long-lasting transgenerational epigenetic</p> <p>12 modifications of a genome."</p> <p>13 A. Okay. I see that, yes.</p> <p>14 Q. Do you agree that's true?</p> <p>15 A. The only thing I would -- I'm</p> <p>16 not sure about so much -- this is, what, ten</p> <p>17 years old?</p> <p>18 I think that -- and that's -- I</p> <p>19 haven't kept up with the literature on</p> <p>20 transgenerational epigenetic modifications.</p> <p>21 I know that's somewhat controversial. It's</p> <p>22 not exactly clear what is transgenerational</p> <p>23 and what's not.</p> <p>24 And this -- so -- but, yes.</p> <p>25 This at the time -- this was written in,</p> | <p>1 Q. It's formally known as</p> <p>2 8-hydroxy-deoxyguanosine, right?</p> <p>3 MS. BROWN: Objection to the</p> <p>4 form.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. In that first sentence there,</p> <p>7 do you see that?</p> <p>8 A. I do see that, yes.</p> <p>9 Q. Doctor, do you dispute</p> <p>10 Dr. Cabrera's conclusion that oxidation of</p> <p>11 DNA can cause damage to DNA?</p> <p>12 A. I --</p> <p>13 MS. BROWN: Objection to the</p> <p>14 form.</p> <p>15 THE WITNESS: This is outside</p> <p>16 my area of expertise. I really can't</p> <p>17 comment on that.</p> <p>18 QUESTIONS BY MR. DOVEL:</p> <p>19 Q. Do you dispute that oxidation</p> <p>20 of DNA can result in mutations and epigenetic</p> <p>21 changes?</p> <p>22 MS. BROWN: Objection to the</p> <p>23 form.</p> <p>24 THE WITNESS: Again, it's --</p> <p>25 it's outside my area of expertise. I</p> |
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| <p>1 what, 2013 -- probably in 2012, this was --</p> <p>2 seemed to be the status in that -- in that</p> <p>3 field.</p> <p>4 (Faraone Exhibit 726 marked for</p> <p>5 identification.)</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. I'm going to mark as</p> <p>8 Exhibit 726 pages 42 and 43 from</p> <p>9 Dr. Cabrera's report.</p> <p>10 MS. BROWN: I'll object to 726,</p> <p>11 one page -- two pages from</p> <p>12 Dr. Cabrera's report.</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. In Dr. Cabrera's report,</p> <p>15 there's a section on acetaminophen and DNA</p> <p>16 oxidation.</p> <p>17 Do you see that?</p> <p>18 A. I do see that, yes.</p> <p>19 Q. And in this he discusses a</p> <p>20 substance called 8-OH-dG.</p> <p>21 Do you see that?</p> <p>22 A. I do see that, yes.</p> <p>23 Q. And your report does not</p> <p>24 address the subject of 8-OH-dG, does it?</p> <p>25 A. I don't think it does.</p> | <p>1 haven't studied this or -- nor is it a</p> <p>2 focus of my report.</p> <p>3 QUESTIONS BY MR. DOVEL:</p> <p>4 Q. When you wrote your report,</p> <p>5 were you aware that, as Dr. Cabrera reports</p> <p>6 here, that increased concentrations of</p> <p>7 acetaminophen in human cord blood are</p> <p>8 associated with increased 8-OH-dG levels?</p> <p>9 MS. BROWN: I object to the</p> <p>10 form of the question.</p> <p>11 THE WITNESS: Yes. That's the</p> <p>12 Anand paper, and I did look at the</p> <p>13 Anand paper.</p> <p>14 QUESTIONS BY MR. DOVEL:</p> <p>15 Q. And the Anand paper showed that</p> <p>16 DNA -- the byproduct of this DNA product</p> <p>17 damage, 8-OH-dG, is correlated with 8 -- with</p> <p>18 acetaminophen exposure, right?</p> <p>19 MS. BROWN: Objection. Form.</p> <p>20 THE WITNESS: I don't recall</p> <p>21 the details of the Anand paper.</p> <p>22 (Faraone Exhibit 742 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. DOVEL:</p> <p>25 Q. I'm going to mark as</p> |

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| <p>1 Exhibit 742 the Anand 2014 paper. 2 I'm going to start with page 3. 3 There's a diagram in the upper right-hand 4 corner. 5 A. Did you say page 3? 6 Q. Yes. 7 A. Okay. Well, I see it. 8 Q. This diagram in the upper 9 right-hand corner shows the pathway by which 10 acetaminophen is metabolized into NAPQI and 11 then results in oxidative stress and DNA 12 damage producing 8-hydroxy-deoxyguanosine, 13 right? 14 A. I see that, yes. 15 Q. Let's turn to page 10. Anand's 16 report, I've got it highlighted in the middle 17 of that paragraph there, found that 18 "increasing levels of 8-hydroxy- 19 deoxyguanosine were associated with higher 20 odds of childhood ADHD." 21 Right? 22 A. So can we look at the table for 23 that? This is -- I don't see that -- 24 Q. Do you see the statement I was 25 pointing to?</p> | <p>1 Q. If acetaminophen has a pathway 2 whereby it causes epigenetic changes, that 3 would mean that genetics were a -- is a 4 mediator of the effects of acetaminophen, 5 right? 6 MS. BROWN: I object to the 7 form of the question. 8 THE WITNESS: It's using 9 genetic in a very vague term. It 10 doesn't mean, for example, that the 11 mother's genotype mediating effects of 12 acetaminophen. 13 All -- what it means is that if 14 this is -- let's assume for a moment 15 that this is true, that acetaminophen 16 exposure gets into the -- 17 acetaminophen gets into the cell. In 18 that case, there's -- an epigenetic 19 mark is placed on one or more genes. 20 That changes the expression of 21 that gene in some way, and that 22 protein, that protein that is no 23 longer the same as it ought to be, 24 that's -- that would be the mediator, 25 not the gene.</p> |
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| <p>1 A. Yeah. I'm just trying to find 2 out actually where he -- that's, I think, in 3 the discussion section. I'm just trying to 4 look at the actual data. 5 Q. Well, let's start with the 6 discussion section. 7 Is that what he writes in the 8 discussion section? 9 A. That's what you have -- this -- 10 increasing levels of -- da-da-da, not 11 glutamate, found to be associated with higher 12 odds -- I see that. It doesn't say how high 13 the odds were, but it does say that. 14 And I can't tell from this 15 whether it was -- adjusted for any confounds 16 or not. I would have to look at the methods 17 to determine that. 18 This looks like one of the 19 papers that has the big multiple comparison 20 problem. There are lots of p-values reported 21 here. 22 So there's a question about, 23 you know -- we would have to look at that to 24 address the significance level -- the meaning 25 of the significance levels for this.</p> | <p>1 The mediator is actually the 2 protein that is then -- that's 3 typically a protein that's talking to 4 another protein and doing something. 5 And there's usually a series of events 6 that occur in the cell that lead to 7 some outcome that if it's relevant to 8 ADHD, obviously, it ought to be 9 relevant to ADHD, and which is 10 something that's, of course, missing 11 from this article, is how this is 12 relevant to ADHD. 13 QUESTIONS BY MR. DOVEL: 14 Q. If -- how is it if we have 15 something that is a -- withdrawn. 16 If we have something that's 17 serving as a mediator between acetaminophen 18 and an effect in causing ADHD, how is it that 19 a sibling-control study would tend to mask or 20 reduce the effects of the -- that are shown 21 in that study? 22 MS. BROWN: Objection to form. 23 THE WITNESS: Well, according 24 to the Sjölander paper, if there is a 25 familial mediator, something that is</p> |

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| <p style="text-align: right;">Page 465</p> <p>1 shared among siblings, an obvious 2 example is something like poverty, 3 then that could -- that would, let's 4 see, reduce the risk ratio that's seen 5 at a population level. 6 And would be considered -- 7 reduced in the sense that it's -- 8 well, it's not quite a confound, but 9 it's equivalent to something being -- 10 in other words, it would be -- it 11 would be reducing an association that 12 ought to be seen but is not seen 13 because there's a familial mediator. 14 But I don't see -- what I 15 haven't seen in anything -- like in 16 this paper or in some of the reports 17 that I've read, is an example of a 18 familial mediator. Because the 19 mediation is occurring in -- that we 20 talk about is occurring in cells 21 presumably -- again, this is all 22 hypothetical, but it's presumably 23 occurring in cells in the brain, and 24 siblings don't share their brains. 25 The brains of two siblings are</p> | <p style="text-align: right;">Page 467</p> <p>1 mediating an effect of a -- that an 2 environmental exposure by as a result of 3 expressing proteins, then would a 4 sibling-control study suppress part of the 5 association? 6 A. I don't understand how -- what 7 I don't understand is how -- again, I use the 8 example of poverty as being familial. 9 Siblings share the same household. If the 10 family is living in poverty, typically they 11 both are living in poverty, although not 12 always. 13 Siblings don't share the same 14 brain. They don't -- their cells are 15 different. They don't necessarily share the 16 same -- they necessarily don't -- they 17 don't -- what we're talking about here is not 18 something that's shared among siblings. So 19 it's -- I don't -- I don't see that as a 20 mediator. 21 And also the other problem with 22 these -- the concern about familial mediators 23 or familial moderators, it's the same issue, 24 is we don't know from the -- the Sjölander 25 paper as to how -- what it -- how serious</p> |
| <p style="text-align: right;">Page 466</p> <p>1 similar, undoubtedly, although we 2 would have to look into that, exactly 3 how similar, but siblings are exposed 4 to many effects that are not shared. 5 And because of that, their brains are 6 not the same. And so any given 7 specific mediator is not necessarily 8 familial. 9 QUESTIONS BY MR. DOVEL: 10 Q. Siblings share genes, right? 11 A. They share 50 percent of their 12 genes, that's correct. On average. But 13 50 percent, yeah. 14 Q. If genes serve as a mediator 15 for an environmental effect, then will a 16 sibling-control study suppress or reduce part 17 of that effect? 18 A. It's not the genes that are 19 mediating it. What's mediating it is the 20 protein that's expressed in the brain. 21 Q. And proteins are expressed 22 based upon genetic instructions in part, 23 right? 24 A. Correct, yes. 25 Q. If we have genes that are</p> | <p style="text-align: right;">Page 468</p> <p>1 this effect is and how dramatic that effect 2 is. 3 And, in fact, I believe -- I 4 believe in the Gustavson paper he refers to 5 it as possibly having effects in either 6 direction. We could look at that. 7 It's -- I haven't seen anything 8 in the -- you know, in the -- I did read 9 the -- you know, the plaintiff reports about 10 this issue of mediation and moderation. I 11 just haven't seen anything that's clearly to 12 me a familial mediator that's working in a 13 biological pathway that's mechanistically 14 related to ADHD. 15 (Faraone Exhibit 733 marked for 16 identification.) 17 QUESTIONS BY MR. DOVEL: 18 Q. I'm going to mark as 19 Exhibit 733 the Baccarelli forest plot. 20 MS. BROWN: Objection to 733. 21 QUESTIONS BY MR. DOVEL: 22 Q. Sir, I want you to assume that 23 this document is a forest plot of the results 24 that are found in Dr. Baccarelli's expert 25 report.</p> |

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| <p>1 A. So this is in his report?</p> <p>2 This --</p> <p>3 Q. No, I want you to assume this</p> <p>4 is a forest plot of the results.</p> <p>5 MS. BROWN: Objection --</p> <p>6 THE WITNESS: I'm not sure --</p> <p>7 I'm confused.</p> <p>8 MS. BROWN: Hold on.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. I want you to assume that --</p> <p>11 THE WITNESS: Okay. You can go</p> <p>12 ahead. I am --</p> <p>13 QUESTIONS BY MR. DOVEL:</p> <p>14 Q. -- each of the studies on the</p> <p>15 left-hand side are addressed by</p> <p>16 Dr. Baccarelli.</p> <p>17 A. Okay.</p> <p>18 Q. That he reports numbers for the</p> <p>19 risk ratio and confidence intervals for each</p> <p>20 of these, and that each of these numbers then</p> <p>21 have been plotted on this diagram.</p> <p>22 Are you with me so far?</p> <p>23 A. So --</p> <p>24 MS. BROWN: Let me just object</p> <p>25 to the question and to the document.</p> | <p>1 THE WITNESS: Let me just take</p> <p>2 a quick look here. Yes, I'm pretty</p> <p>3 sure that's the case.</p> <p>4 Yes, it is the case.</p> <p>5 QUESTIONS BY MR. DOVEL:</p> <p>6 Q. If we look at the results of</p> <p>7 these studies as a whole rather than just</p> <p>8 look at any one study, does it suggest a</p> <p>9 positive risk for the association between</p> <p>10 acetaminophen and ADHD?</p> <p>11 MS. BROWN: I object to the</p> <p>12 form and to the document.</p> <p>13 THE WITNESS: So -- well, first</p> <p>14 a comment about the way -- the data</p> <p>15 presentation is that you've got</p> <p>16 multiple data points from the same</p> <p>17 study, which -- so there's -- there</p> <p>18 actually aren't as many -- you know,</p> <p>19 which can -- I'm not saying anybody</p> <p>20 was intending to mislead. Don't get</p> <p>21 me wrong. But I'm just saying that</p> <p>22 can be a little bit misleading as to</p> <p>23 what -- as to the -- as to these</p> <p>24 findings here.</p> <p>25 With that said -- you're going</p> |
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| <p>1 Go ahead.</p> <p>2 THE WITNESS: Well, you've</p> <p>3 objected. Okay.</p> <p>4 Just to be clear, so what</p> <p>5 you're saying is that somebody took</p> <p>6 the numbers in Dr. Baccarelli's</p> <p>7 report, entered them into some</p> <p>8 software and computed this -- computed</p> <p>9 this graphic here?</p> <p>10 QUESTIONS BY MR. DOVEL:</p> <p>11 Q. This is the result, yes.</p> <p>12 A. This is -- okay. This is --</p> <p>13 okay. I will take you at your word on that.</p> <p>14 And the question, what are</p> <p>15 we -- what would you like to know about this?</p> <p>16 Q. Now, if we look at this, we see</p> <p>17 that a number of the results are</p> <p>18 statistically significant and some are not,</p> <p>19 right?</p> <p>20 A. Correct.</p> <p>21 Q. Of the results that are</p> <p>22 statistically significant, do they all show a</p> <p>23 positive risk ratio?</p> <p>24 MS. BROWN: I object to the</p> <p>25 form.</p> | <p>1 to have to repeat the question again</p> <p>2 because I was focusing on this issue</p> <p>3 of multiple data points in the same</p> <p>4 study.</p> <p>5 So --</p> <p>6 QUESTIONS BY MR. DOVEL:</p> <p>7 Q. If we examined the results of</p> <p>8 these studies as a whole and do not just</p> <p>9 focus on one study, do the results suggest an</p> <p>10 association between acetaminophen and ADHD?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form.</p> <p>13 THE WITNESS: This is not how</p> <p>14 it's typically done. Typically, one</p> <p>15 computes a meta-analysis, and then we</p> <p>16 have a pooled -- we have a pooled risk</p> <p>17 ratio, and from that pooled risk --</p> <p>18 from that pooled risk -- ah, I'm</p> <p>19 getting tongue-tied here.</p> <p>20 From that pooled risk ratio, we</p> <p>21 drew a conclusion. And if we do -- we</p> <p>22 take the most recent meta-analysis by</p> <p>23 Ricci, et al., they do -- they do --</p> <p>24 they do compute a pooled and</p> <p>25 significant odds ratio across the</p> |

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| <p>1 studies that they looked at.</p> <p>2 QUESTIONS BY MR. DOVEL:</p> <p>3 Q. A positive risk ratio, right?</p> <p>4 A. That's correct. Which is --</p> <p>5 they actually -- I believe they compute a</p> <p>6 few. They kind of divide the meta-analysis</p> <p>7 into series.</p> <p>8 And in some -- in several of</p> <p>9 the meta-analyses, the results are also</p> <p>10 substantially heterogenous, meaning that</p> <p>11 they differ significantly from one study to</p> <p>12 the next. The technical term is all of the</p> <p>13 studies aren't estimating the same underlying</p> <p>14 risk ratio.</p> <p>15 Q. All right. Now, you've</p> <p>16 explained about pooled risk ratios and</p> <p>17 meta-analysis. My question is, if we were to</p> <p>18 examine these studies as a whole, do they</p> <p>19 suggest a positive risk?</p> <p>20 MS. BROWN: Objection to the</p> <p>21 form.</p> <p>22 THE WITNESS: Yes, I would -- I</p> <p>23 guess I meant to say is that this data</p> <p>24 layout is consistent with the</p> <p>25 meta-analyses, except it's hard to</p> | <p>1 QUESTIONS BY MR. DOVEL:</p> <p>2 Q. This plot includes the data on</p> <p>3 studies where they had information on a</p> <p>4 dose-response ratio that were reported in</p> <p>5 Dr. Baccarelli's report.</p> <p>6 A. Okay.</p> <p>7 MS. BROWN: Objection to form.</p> <p>8 QUESTIONS BY MR. DOVEL:</p> <p>9 Q. In each case, does -- did it --</p> <p>10 was a dose-response effect shown?</p> <p>11 MS. BROWN: Objection to the</p> <p>12 form of the question.</p> <p>13 THE WITNESS: Well, let's -- I</p> <p>14 would have to take a look at them one</p> <p>15 by one here.</p> <p>16 So the problems with the</p> <p>17 dose-response data are -- well, first,</p> <p>18 number one, dose-response data are</p> <p>19 also confounded in the same ways that</p> <p>20 the original -- these -- the other</p> <p>21 aspects of the study are confounded.</p> <p>22 Confounds by indication,</p> <p>23 confounds by genetics, maternal aging,</p> <p>24 so forth.</p> <p>25 Second, for example, if you</p> |
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| <p>1 interpret because of the -- anyway, I</p> <p>2 won't give out the detail about the</p> <p>3 multiple studies. I'm sorry, the</p> <p>4 duplicated observations from multiple</p> <p>5 studies -- from the same study.</p> <p>6 I think the answer to your</p> <p>7 question is -- the simplest answer is,</p> <p>8 yes, it's consistent with that.</p> <p>9 QUESTIONS BY MR. DOVEL:</p> <p>10 Q. Now, you recognized in your</p> <p>11 report that the issue of whether there's a</p> <p>12 dose-response effect was relevant to</p> <p>13 causation, right?</p> <p>14 A. Yes, that's a criteria in the</p> <p>15 Bradford Hill.</p> <p>16 Q. And you concluded that looking</p> <p>17 at the data that there was no dose-response</p> <p>18 that was currently shown, right?</p> <p>19 A. That's correct.</p> <p>20 (Faraone Exhibit 737 marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. DOVEL:</p> <p>23 Q. I'm going to mark as</p> <p>24 Exhibit 737 the dose response forest plot.</p> <p>25 MS. BROWN: I object to 737.</p> | <p>1 look at Liew, at the top, the</p> <p>2 confidence intervals are clearly</p> <p>3 overlapping, indicating no</p> <p>4 differences, no significant</p> <p>5 differences between the two doses.</p> <p>6 The same is true for the second</p> <p>7 set of studies. Same is true for the</p> <p>8 third set of studies. The fourth set</p> <p>9 of studies. The fifth set of studies.</p> <p>10 The sixth set of studies. In fact, if</p> <p>11 you look at the Ystrom data, the 22 --</p> <p>12 the 28-day data overlaps with the</p> <p>13 no-use data and the 8- to 14-day data.</p> <p>14 So each of these is true.</p> <p>15 Looking at all of these studies we see</p> <p>16 substantial -- not just a little</p> <p>17 overlap, but a substantial overlap</p> <p>18 between the confidence intervals,</p> <p>19 which indicate that there's no</p> <p>20 statistically reliable difference</p> <p>21 between those dose levels.</p> <p>22 MS. BROWN: Counsel, I believe</p> <p>23 we're out of time. Can we find out</p> <p>24 how long we've been on the record?</p> <p>25 VIDEOGRAPHER: We've been on</p> |

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| <p>1 the record for 7 hours and 1 minute. 2 MS. BROWN: Okay. We're done. 3 I just have a few follow-ups. 4 Do you want to take a break, or 5 should we just keep going? 6 MR. DOVEL: It's up to you. 7 MS. BROWN: Okay. Are you good 8 to answer few final questions? 9 THE WITNESS: I'm ready. I'm 10 ready. 11 MS. BROWN: Okay. 12 CROSS-EXAMINATION 13 QUESTIONS BY MS. BROWN: 14 Q. Just a few final questions from 15 me, Dr. Faraone, and we'll get you out of 16 here. 17 And I think I'm not wearing 18 my -- 19 All right. Good evening, 20 Dr. Faraone. How are you holding up? 21 A. I'm doing fine. Thank you. 22 I'm doing fine. 23 Q. We've been here a while now. I 24 just have a few follow-up questions. 25 Earlier this morning you were</p> | <p>1 A. I do, yes. 2 Q. Okay. To be clear, 3 Dr. Faraone, as an ADHD expert, based on your 4 review of the totality of the literature 5 contained in your expert report, do you 6 believe it's risky for a pregnant woman to 7 take acetaminophen during pregnancy? 8 A. I do not. 9 Q. And why is that? 10 A. Because as detailed in my 11 report, the evidence is clear to me that 12 there's no evidence for acetaminophen as 13 increasing the risk -- I'm sorry, 14 acetaminophen used by mothers during 15 pregnancy as increasing the risk for 16 offspring and ADHD. 17 MS. BROWN: Thanks very much, 18 Doctor. I have no further questions. 19 THE WITNESS: Okay. 20 REDIRECT EXAMINATION 21 QUESTIONS BY MR. DOVEL: 22 Q. I've got just a few follow-ups. 23 A. Please. 24 Q. In your view, because 25 acetaminophen is not risky to take, do you</p> |
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| <p>1 asked about a chart that counsel was creating 2 on the ELMO regarding what pregnant women 3 might do during their pregnancy. 4 Do you recall that chart? 5 A. I do recall that, yes. 6 Q. And do you recall questions 7 about whether or not they would or would not 8 follow advice of their doctors? 9 A. I do. 10 Q. Okay. Dr. Faraone, are you a 11 medical doctor? 12 A. I'm not. I'm a psychologist. 13 Q. Okay. Do you give medical 14 recommendations to pregnant women about 15 medicine? 16 A. I do not. I do not. 17 Q. In terms of whether or not a 18 pregnant woman would or would not follow the 19 advice of her physician, would you defer to a 20 clinician for those questions? 21 A. Absolutely. 22 Q. You were asked a series of 23 questions, and you gave some testimony about 24 risky behavior. 25 Do you recall that?</p> | <p>1 have any basis for concluding that women with 2 ADHD are more likely to take acetaminophen 3 when they're pregnant than when they're not 4 pregnant? 5 A. Well, we know from the Leppart 6 data the genetics of ADHD predict use of 7 acetaminophen -- use of acetaminophen by 8 women during pregnancy. That's one source of 9 data that we have there. 10 Q. My question is not about 11 whether they would use it during pregnancy. 12 A. Sorry. 13 Q. Any study that would 14 demonstrate that they would differentially 15 use it; that is, that they would use it more 16 often when they're pregnant than when they're 17 not pregnant? 18 MS. BROWN: Objection to the 19 form. 20 THE WITNESS: No, I don't know 21 of a study of that sort. 22 QUESTIONS BY MR. DOVEL: 23 Q. Do you have any basis to 24 conclude that that's true? 25 MS. BROWN: Objection to the</p> |

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1 form.

2 THE WITNESS: Only my expert
3 opinion based upon my three decades of
4 working with ADHD.

5 QUESTIONS BY MR. DOVEL:

6 Q. And what about these three
7 decades would tell you that AD -- women with
8 ADHD will take more acetaminophen when
9 they're pregnant than when they're not
10 pregnant?

11 A. I gave it as -- in the -- this
12 is the section of the report dealing with the
13 negative controls. I was talking about
14 potential confounds, my concern about
15 potential confounds. And I just gave this as
16 an example of a potential confound.

17 It wasn't -- it wasn't meant to
18 be given in the sense of, this is a hard fact
19 that has been documented in the literature.

20 Q. Well, I want to know what your
21 experience suggests that women with ADHD take
22 more acetaminophen when they're pregnant than
23 when they're not.

24 MS. BROWN: Objection to the
25 form of the question.

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1 CERTIFICATE

2 I, CARRIE A. CAMPBELL, Registered
3 Diplomat Reporter, Certified Realtime
4 Reporter and Certified Shorthand Reporter, do
5 hereby certify that prior to the commencement
6 of the examination, Stephen V. Faraone,
7 Ph.D., was duly sworn by me to testify to the
8 truth, the whole truth and nothing but the
9 truth.

10 I DO FURTHER CERTIFY that the
11 foregoing is a verbatim transcript of the
12 testimony as taken stenographically by and
13 before me at the time, place and on the date
14 hereinbefore set forth, to the best of my
15 ability.

16 I DO FURTHER CERTIFY that I am
17 neither a relative nor employee nor attorney
18 nor counsel of any of the parties to this
19 action, and that I am neither a relative nor
20 employee of such attorney or counsel, and
21 that I am not financially interested in the
22 action.

23 CARRIE A. CAMPBELL,
24 NCRA Registered Diplomat Reporter
25 Certified Realtime Reporter
California Certified Shorthand
Reporter #13921
Missouri Certified Court Reporter #859
Illinois Certified Shorthand Reporter
#084-004229
Texas Certified Shorthand Reporter #9328
Kansas Certified Court Reporter #1715
New Jersey Certified Court Reporter
#30X100242600
Louisiana Certified Court Reporter
#2021012
Notary Public
Dated: September 11, 2023

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1 THE WITNESS: As I said, it
2 was -- it was -- it was only an
3 example that I thought of that
4 could -- where -- as described in
5 there in the -- in the document. I
6 don't really have much more to say
7 about that.

8 QUESTIONS BY MR. DOVEL:

9 Q. Can you --

10 MS. BROWN: Counsel, I believe
11 you're out of time. I understand you
12 only get the amount of time I used,
13 and you've exceeded that.

14 So we need to go off the
15 record.

16 VIDEOGRAPHER: The time right
17 now is 5:44 p.m. We are off the
18 record.
19 (Deposition concluded at 5:44 p.m.)
20 -----
21
22
23
24
25

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1 INSTRUCTIONS TO WITNESS

2 DATE: September 11, 2023

3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it. You are signing
10 same subject to the changes you have noted on
11 the errata sheet, which will be attached to
12 your deposition.

13 It is imperative that you return
14 the original errata sheet to the deposing
15 attorney within thirty (30) days of receipt
16 of the deposition transcript by you. If you
17 fail to do so, the deposition transcript may
18 be deemed to be accurate and may be used in
19 court.
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21
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23
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25

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| 1 | ACKNOWLEDGMENT OF DEPONENT | 1 | ----- |
| 2 | | 2 | LAWYER'S NOTES |
| 3 | | 3 | ----- |
| 4 | I, _____, do | 4 | PAGE LINE |
| 5 | hereby certify that I have read the foregoing | 5 | _____ |
| 6 | pages and that the same is a correct | 6 | _____ |
| 7 | transcription of the answers given by me to | 7 | _____ |
| 8 | the questions therein propounded, except for | 8 | _____ |
| 9 | the corrections or changes in form or | 9 | _____ |
| 10 | substance, if any, noted in the attached | 10 | _____ |
| 11 | Errata Sheet. | 11 | _____ |
| 12 | | 12 | _____ |
| 13 | _____ Stephen V. Faraone, Ph.D. DATE | 13 | _____ |
| 14 | | 14 | _____ |
| 15 | Subscribed and sworn to before me this | 15 | _____ |
| 16 | _____ day of _____, 20 ____. | 16 | _____ |
| 17 | My commission expires: _____ | 17 | _____ |
| 18 | | 18 | _____ |
| 19 | Notary Public | 19 | _____ |
| 20 | | 20 | _____ |
| 21 | | 21 | _____ |
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| 23 | | 23 | _____ |
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| 25 | | 25 | _____ |

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